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Ref. No: ML-2022-06248

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: 26/07/2022

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Certificate/Report

RESULTS REPORTED RELATED ONLY TO ITEMS TESTED

COMPANY NAME

: NANOCARE SA

ADDRESS

: 3 HESKETH ROAD, WESTMEAD, PINETOWN, 3610

SUBJECT

: OUANTITATIVE SUSPENSION TEST FOR THE EVALUATION OF

BACTERICIDAL ACTIVITY OF CHEMICAL DISINFECTANTS AND

ANTISEPTICS USED IN FOOD, INDUSTRIAL, DOMESTIC AND

INSTITUTIONAL AREAS SANS 51276:2021 (EN1276:2019): DILUTION-

NEUTRALIZATION METHOD

MARKED

: NANOCARE/NANOPURE EXP 01/05/2025

BATCH

ACTIVE INGREDIENT

: 51% NaDCC, 0.016% NANOSILVER

DILUENT RECOMMENDED

: POTABLE WATER

APPEARANCE

: WHITE TABLETS

DILUENT USED

: STANDARDIZED HARD WATER

CONCENTRATIONS TESTED : 25PPM, 250PPM, 500PPM

APPEARANCE OF DILUTIONS: COLOURLESS, HOMOGENOUS, NO PRECIPITATE OBSERVED

NEUTRALIZING AGENT

: NEUTRALIZING FLUID

SOILING CONDITIONS

: DIRTY CONDITIONS

STORAGE CONDITIONS

: STORE IN A COOL DRY PLACE, AWAY FROM FOODSTUFFS

INSTRUCTED BY

: SHAUN

LAB NO.

: 949027

RECEIVED ON

: 28/06/2022

DATE ANALYSED

: 29/06/2022

EXPERIMENTAL CONDITIONS:

Obligatory conditions

test organisms:

Enterococcus hirae ATCC 10541

Escherichia coli ATCC 10536

Pseudomonas aeruginosa ATCC 15442

Staphylococcus aureus ATCC 6538

Test temperature:

20°C

Contact time:

5 minutes

Interfering substance:

3g/l Bovine serum albumin (Dirty conditions)

Test incubation temperature:

37°C

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E: joanne.barton@za.bureauveritas.com

M and L Laboratory Services (Pty) Ltd Reg No. 1974/001476/07 VAT No. 478013505

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PASS REQUIREMENTS:

The product shall demonstrate at least a 5 decimal log reduction when diluted with hard water/or undiluted and tested under obligatory test conditions. At least one of the test concentrations will demonstrate a log reduction of less than 5 log.

TEST VALIDITY

For each test organism:

- N is between 1.5×10^8 and 5.0×10^8 (8.17 $\leq \log N \leq 8.70$)
- N_0 is between 1.5x10⁷ and 5.0x10⁷ (7.17 \le log N \le 7.70)
- N_{V0} is between 30 and 160 (3.0x10¹ and 1.6x10²)
- A, B, C are equal to or greater than 0.5xN_{vo}
- Control of weighted mean counts: quotient is not lower than 5 and not higher than 15

RESULTS:

Escherichia coli ATCC 10536

Table 1: Nand No values

| Dilution | Vc1 | Vc2 | Average N(wm) | Log N | N ₀ (N/10) | Log No |
|-------------------|----------------|------------------|----------------------|-------|-----------------------|--------|
| 10-6 | 241 | 231 | 0.0-108 | 0.44 | 0.0.107 | 7.44 |
| 10-7 | 35 | 29 | -2.8×10^{8} | 8.44 | 2.8x10 ⁷ | 7.44 |
| Is Log N between | een 8.17 and 8 | 3.70: Yes | | | | |
| Is Log No between | en 7.17and 7 | .70: Yes | | | i | |
| Control of weight | ghted mean co | ounts: 7.38 | | | | |

Table 2: Test Log Reduction Values

| Product Concentration | Vc1 | Vc2 | Na (Ave Vc1&Vc2x10) | Log Na | Log Reduction (No: 7.44) |
|--------------------------|------|------|------------------------|--------|-----------------------------|
| 25ppm | >330 | >330 | >3300 | >3.52 | <3.92 |
| 250ppm | <14 | <14 | <140 | <2.15 | >5.29 |
| 500ppm | <14 | <14 | <140 | <2.15 | >5.29 |

Pseudomonas aeruginosa ATCC 15442

Table 3: Nand No values

| Dilution | Vc1 Vc2 Average N(wm) | | THE RESIDENCE OF THE PARTY OF T | Log N | No (N/10) | Log No |
|-----------------|-----------------------|--------------------|--|-------|---------------------|--------|
| 10-6 | 309 | 296 | 2.7-108 | 8.57 | 0.7107 | 7.57 |
| 10-7 | 42 | 45 | $-3.7x10^8$ | 0.37 | 3.7x10 ⁷ | 7.57 |
| Is Log Nbetwe | en 8.17 and 8 | .70: Yes | | | | |
| Is Log No betwo | een 7.17and 7 | 7.70: Yes | | | | -1 |
| Control of wei | ghted mean co | ounts: 6.95 | | | | |



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RESULTS REPORTED RELATED ONLY TO ITEMS TESTED

Table 4: Test Log Reduction Values

| Product Concentration | Vc1 | Vc2 | Na (Ave Vc1&Vc2x10) | Log Na | Log Reduction (No:7.57) |
|--------------------------|------|------|------------------------|--------|-------------------------|
| 25ppm | >330 | >330 | >3300 | >3.52 | <4.05 |
| 250ppm | <14 | <14 | <140 | <2.15 | >5.42 |
| 500ppm | <14 | <14 | <140 | <2.15 | >5.42 |

Staphylococcus aureus ATCC 6538

Table 5: Nand No values

| Dilution | Vc1 | Vc2 | Average N(wm) | Log N | N ₀ (N/10) | Log No |
|------------------|----------------|----------------|-----------------------|--------|-----------------------|--------|
| 10-6 | 255 | 264 | 2.0108 | 0.40 | 0.0-107 | 7.40 |
| 10-7 | 24 | 29 | - 2.6x10 ⁸ | 8.42 | 2.6x10 ⁷ | 7.42 |
| Is Log Nbetwee | en 8.17 and 8. | 70: Yes | | 27 100 | - | |
| Is Log No betwe | en 7.17and 7. | 70: Yes | | | | *** |
| Control of weigh | shted mean co | unts: 9.79 | | | | |

Table 6: Test Log Reduction Values

| Product Concentration | Vc1 | Vc2 | Na (Ave Vc1&Vc2x10) | Log Na | Log Reduction (No:7.42) |
|--------------------------|------|------|------------------------|--------|-------------------------|
| 25ppm | >330 | >330 | >3300 | >3.52 | <3.90 |
| 250ppm | <14 | <14 | <140 | <2.15 | >5.27 |
| 500ppm | <14 | <14 | <140 | <2.15 | >5.27 |

Enterococcus hirae ATCC 10541

Table 7: Nand No values

| Dilution | Vc1 | Vc2 | Average N(wm) | Log N | N ₀ (N/10) | Log No | |
|-------------------|----------------|----------------|----------------------|-------|-----------------------|--------|--|
| 10-6 | 166 | 174 | 0.0-10% | 0.00 | 0.0.107 | T 02 | |
| 10-7 | 25 | 21 | -2.0×10^{8} | 8.30 | 2.0x10 ⁷ | 7.30 | |
| Is Log Nbetwee | en 8.17 and 8. | 70: Yes | | | | | |
| Is Log No between | en 7.17and 7. | 70: Yes | | | | | |
| Control of weig | ghted mean co | ants: 7.39 | | | | | |

Table 8: Test Log Reduction Values

| Product Concentration | Vc1 | Vc2 | Na (Ave Vc1&Vc2x10) | Log Na | Log Reduction (No:7.30) |
|--------------------------|------|------|------------------------|--------|-------------------------|
| 25ppm | >330 | >330 | >3300 | >3.52 | <3.78 |
| 250ppm | <14 | <14 | <140 | <2.15 | >5.15 |
| 500ppm | <14 | <14 | <140 | <2.15 | >5.15 |



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VALIDATIONS AND CONTROLS

Table 9: Enterococcus hirae ATCC 10541

| Valida | Validation suspension | | | Experimental Conditions Control A | | | alizer Co | ntrol B | Method Validation C | | |
|---------|-----------------------|---------|---------|-----------------------------------|-----|-----|-----------|---------|---------------------|----|-----|
| | | Ave | | | Ave | | 0 | Ave | | | Ave |
| Vc1 | 85 | 00 | Vc1 | 81 | 80 | Vc1 | 74 | 75.5 | Vc1 | 66 | 70 |
| Vc2 | 91 | - 88 | Vc2 | 79 | 80 | Vc2 | 77 | 75.5 | Vc2 | 74 | 70 |
| 0.5x88 | =44 | | | | | | | | | | |
| s the N | vo value | between | 30-160: | YES | | | | | | | |

Is the Experimental Condition A≥0.5xNvo value: YES

Is the Neutralizer Condition B≥0.5xNvo value: YES

Is the Method Validation C≥0.5xNvo value: YES

Table 10: Escherichia coli ATCC 10536

| Valida | ition susp | ension | Experimental Conditions Control A | | | Neutr | alizer Co | ntrol B | Method Validation | | |
|----------|------------|-----------|-----------------------------------|----------|------------------|-------|-----------|-------------------|-------------------|----|-----|
| | | Ave | | | Ave | | | Ave | | | Ave |
| Vc1 | 104 | 108 | Vc1 | 92 | 95 | Vc1 | 94 | 100 | Vc1 | 88 | 0.4 |
| Vc2 | 112 | 100 | Vc2 | 98 | 95 | Vc2 | 106 | 100 | Vc2 | 80 | 84 |
| 0.5x10 | 8=54 | | | | | | | Park time Francis | RECORDS | | |
| Is the N | vo value | between | 30-160: | YES | | | | | | | |
| Is the E | xperimen | ital Cond | ition A≥0 | .5xNvo | value: YE | S | | | | | |
| Is the N | eutralize | r Conditi | on B≥0.5 | xNvo va | lue: YES | | | | | | |
| Is the A | 1ethod Va | alidation | C>0.5xN | vo value | · VES | | | | | | |

Table 11: Pseudomonas aeruginosa ATCC 15442

| Valida | tion susp | ension | | perimen tions Cor | | Neutra | alizer Co | ntrol B | Metho | d Valida | tion C |
|--------|-----------|--------|-----|----------------------|-----|--------|-----------|---------|-------|----------|--------|
| | | Ave | | | Ave | | | Ave | | | Ave |
| Vc1 | 96 | 00 | Vc1 | 80 | 9.4 | Vc1 | 84 | 00 | Vc1 | 69 | 7.1 |
| Vc2 | 102 | 99 | Vc2 | 88 | 84 | Vc2 | 96 | 90 | Vc2 | 73 | /1 |

0.5x99=49.5

Is the Nvo value between 30-160: YES

Is the Experimental Condition A≥0.5xNvo value: YES

Is the Neutralizer Condition B≥0.5xNvo value: YES

Is the Method Validation C≥0.5xNvo value: YES





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Table 12: Staphylococcus aureus ATCC 6538

| Valida | tion susp | ension | | perimentions Con | | Neutr | alizer Co | ntrol B | Method Validation | | |
|-----------|-----------|------------|-----------|------------------|------------|-------|-----------|---------|-------------------|----|------|
| | | Ave | | | Ave | | | Ave | | | Ave |
| Vc1 | 112 | 100 | Vc1 | 98 | 0.0 | Vc1 | 99 | 101 | Vc1 | 64 | CCE |
| Vc2 | 106 | 109 | Vc2 | 94 | 96 | Vc2 | 103 | 101 | Vc2 | 69 | 66.5 |
| 0.5x10 | 9=54.5 | | F | | | | 0 | | | | |
| Is the N | vo value | between | 30-160: | YES | | | | | | | |
| Is the Ex | xperimen | tal Condi | ition A≥0 | .5xNvo v | value: YES | 3 | | | | | |
| Is the N | eutralize | r Conditio | on B≥0.5 | xNvo val | ue: YES | | | | | | |
| Is the N | lethod Va | lidation | C≥0.5xN | vo value: | YES | | | | | | |

Conclusion

- The product tested at a dilution of **250ppm complied** with the criteria indicated under the "Pass Requirements" of SANS 51276:2021 (EN 1276:2019) standard (obligatory dirty conditions) which requires at least a 99.999% kill (5 log reduction).
- The mean reduction of six replicates with the limiting test organism *Staphylococcus aureus* was 3.1 x 10⁵. *Pseudomonas aeruginosa, Enterococcus hirae* and *Escherichia coli* were tested once and showed a 5 log reduction or more at a lower concentration than *Staphylococcus aureus*.

TECHNICAL SIGNATORY

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RESULTS REPORTED RELATED ONLY TO ITEMS TESTED

COMPANY NAME

: NANOCARE SA

ADDRESS

: 3 HESKETH ROAD, WESTMEAD, PINETOWN, 3610

SUBJECT

: QUANTITATIVE SUSPENSION TEST FOR THE EVALUATION OF

FUNGICIDAL ACTIVITY OF CHEMICAL DISINFECTANTS

AND ANTISEPTICS USED IN FOOD, INDUSTRIAL, DOMESTIC AND INSTITUTIONAL AREAS SANS 51650:2011 (EN1650:2008): DILUTION-

NEUTRALIZATION METHOD

MARKED

: NANOCARE/NANOPURE EXP 01/05/2025

BATCH

: 18901

ACTIVE INGREDIENT

: 51% NaDCC, 0.016% NANOSILVER

DILUENT USED

: STANDARDIZED HARD WATER

APPEARANCE

: WHITE TABLETS

DILUENT RECOMMENDED

: POTABLE WATER

CONCENTRATIONS TESTED : 25PPM, 250PPM & 500PPM

STORAGE CONDITIONS

: KEEP IN A DRY PLACE AWAY FROM FOODSTUFFS

APPEARANCE OF MIXTURE : COLOURLESS, HOMOGENOUS, NO PRECIPITATE OBSERVED

SOILING CONDITIONS

: PRODUCT NOT TESTED ON SOILED CONDITIONS

NEUTRALIZING AGENT

: NEUTRALIZING FLUID

INSTRUCTED BY

LAB NO.

: SHAUN : 949027

RECEIVED ON

: 28/06/2022

DATE ANALYSED

: 29/06/2022

EXPERIMENTAL CONDITIONS:

Obligatory conditions

test organisms:

Candida albicans ATCC 10231

Aspergillus brasiliensis ATCC 16404

Test temperature:

20°C

Contact time:

15 minutes

Interfering substance:

0.3g/l Bovine serum albumin (Clean conditions)

Test incubation temperature:

30°C

PASS REQUIREMENTS:

The product shall demonstrate at least a 4 decimal log reduction when diluted with hard water/or undiluted and tested under obligatory test conditions. At least one of the test concentrations will demonstrate a log reduction of less than 4 log.



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Date

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RESULTS REPORTED RELATED ONLY TO ITEMS TESTED

TEST VALIDITY

For each test organism:

- *N* is between 1.5×10^7 and 5.0×10^7 ($7.17 \le \log N \le 7.70$)
- N_0 is between 1.5x10⁶ and 5.0x10⁶ (6.17 \le log N \le 6.70)
- N_{VO} is between 30 and 160 (3.0x10¹ and 1.6x10²)
- A, B, C are equal to or greater than 0.5xNvo
- Control of weighted mean counts: quotient is not lower than 5 and not higher than 15

RESULTS:

Candida albicans ATCC 10231

Table 13: Nand No values

| Dilution | Vc1 | Vc2 | Average N(wm) | Log N | N ₀ (N/10) | Log No |
|------------------|---------------|------------------|--------------------|-------|-----------------------|--------|
| 10-5 | 226 | 232 | 0.4-107 | 7.00 | 2.4-126 | 0.00 |
| 10-6 | 24 | 26 | -2.4×10^7 | 7.38 | 2.4×10^{6} | 6.38 |
| Is Log N between | een 7.17 and | 7.70: Yes | | | | |
| Is Log No betwe | een 6.17and 6 | 5.70: Yes | | | 1517 | |
| Control of wei | ghted mean co | ounts: 9.16 | | | | |

Table 14: Test Log Reduction Values

| Product Concentration | Vc1 | Vc2 | Na (Ave Vc1&Vc2x10) | Log Na | Log Reduction (No: 6.38) |
|--------------------------|------|------|------------------------|--------|--------------------------|
| 25ppm | >330 | >330 | >3300 | >3.52 | <2.86 |
| 250ppm | <14 | <14 | <140 | <2.15 | >4.23 |
| 500ppm | <14 | <14 | <140 | <2.15 | >4.23 |

Aspergillus brasiliensis ATCC 16404

Table 15: Nand No values

| Dilution | Vc1 | Vc2 | Average N(wm) | Log N | N ₀ (N/10) | Log No |
|-----------------|---------------|------------------|-----------------------|-------|-----------------------|--------|
| 10-5 | 144 | 139 | 2 Ov 1 O7 | 7.30 | 2.0-106 | 0.20 |
| 10-6 | 24 | 29 | - 2.0x10 ⁷ | 7.30 | 2.0x10 ⁶ | 6.30 |
| Is Log Nbetwe | en 7.17 and 7 | .70: Yes | | | | |
| Is Log No betwe | een 6.17and 6 | 6.70: Yes | 200 | | | |
| Control of wei | ghted mean co | ounts: 5.34 | | | | |

TECHNICAL SIGNATORY

·····

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Table 16: Test Log Reduction Values

| Product Concentration | Vc1 | Vc2 | Na (Ave Vc1&Vc2x10) | Log Na | Log Reduction (No: 6.30) |
|--------------------------|------|------|------------------------|--------|--------------------------|
| 25ppm | >165 | >165 | >1650 | >3.22 | <3.08 |
| 250ppm | 19 | 16 | 175 | 2.24 | 4.06 |
| 500ppm | <14 | <14 | <140 | <2.15 | >4.15 |

VALIDATIONS AND CONTROLS

Table 17: Candida albicans ATCC 10231

| Valida | tion susp | pension | | perimentions Co | | Neutra | alizer Co | ntrol B | Metho | od Valida | ation C |
|-----------|-----------|------------|-----------|-----------------|------------|-----------------|-----------|---------|-------|-----------|-----------|
| | | Ave | | | Ave | | | Ave | | | Ave |
| Vc1 | 78 | 00 | Vc1 | 70 | COF | Vc1 | 64 | CCE | Vc1 | 64 | 62.5 |
| Vc2 | 86 | 82 | Vc2 | 67 | 68.5 | Vc2 | 69 | 66.5 | Vc2 | 61 | 62.3 |
| 0.5x82 | =41 | | | | | | | | | | |
| Is the N | vo value | between | 30-160: | YES | | 11-0-1-100 Tar2 | 300 | | | | 1100/1902 |
| Is the Ex | kperimer | ntal Condi | ition A≥0 | .5xNvo v | value: YES | 3 | | | | | |
| Is the N | eutralize | r Conditi | on B≥0.5 | xNvo val | lue: YES | | | | | | |
| Is the N | lethod Va | alidation | C≥0.5xN | vo value: | YES | | | | | | |

Table 18: Aspergillus brasiliensis ATCC 16404

| Valida | tion susp | ension | | tions Co | | Neutra | alizer Co | ntrol B | Metho | od Valida | ation C |
|-----------|-----------|-------------|-----------|-----------|------------|--------|-----------|---------|-------|-----------|---------|
| | | Ave | | | Ave | | | Ave | | | Ave |
| Vc1 | 69 | CC | Vc1 | 55 | 56 | Vc1 | 61 | - 63 | Vc1 | 54 | 56.5 |
| Vc2 | 63 | - 66 | Vc2 | 57 | 36 | Vc2 | 65 | 03 | Vc2 | 59 | 36.5 |
| 0.5x66 | =33 | | | | | | | | | | |
| Is the N | vo value | between | 30-160: | YES | | | | | | | |
| Is the Ex | xperimen | ıtal Condi | ition A≥0 | .5xNvo v | value: YES | 3 | | | | | |
| Is the N | eutralize | r Conditio | on B≥0.5 | xNvo val | ue: YES | | | | | | 0 8000 |
| Is the M | lethod Va | alidation (| C≥0.5xN | vo value: | YES | | | | | | |
| | | | | | | | | | | | |

Conclusion

- The product tested at a dilution of 250ppm complied with the criteria indicated under the "Pass Requirements" of SANS 51650:2011 (EN1650:2008) standard (obligatory conditions) which requires at least a 99.99% kill (4 log reduction).
- The mean reduction of six replicates with the limiting test organism *Aspergillus brasiliensis* was 1.2 x 10⁴. *Candida albicans* was tested once and showed a 4 log reduction at a lower concentration than *Aspergillus brasiliensis*.



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RESULTS REPORTED RELATED ONLY TO ITEMS TESTED

COMPANY NAME

: NANOCARE SA

ADDRESS

: 3 HESKETH ROAD, WESTMEAD, PINETOWN, 3610

SUBJECT

: OUANTITATIVE SUSPENSION TEST FOR THE EVALUATION OF

SPORICIDAL ACTIVITY OF CHEMICAL DISINFECTANTS USED IN FOOD, INDUSTRIAL, DOMESTIC AND INSTITUTIONAL AREAS SANS 53704:2006 (EN13704:2002): DILUTION- NEUTRALIZATION METHOD

MARKED

: NANOCARE/NANOPURE EXP 01/05/2025

BATCH

: 18901

ACTIVE INGREDIENT

: 51% NaDCC, 0.016% NANOSILVER

DILUENT RECOMMENDED

: POTABLE WATER

CONCENTRATIONS TESTED

: 25PPM, 250PPM & 500PPM

APPEARANCE

: WHITE TABLETS

DILUENT USED

: STANDARDIZED HARD WATER

APPEARANCE OF MIXTURE : COLOURLESS, HOMOGENOUS, NO PRECIPITATE OBSERVED

: STORE IN A COOL DRY PLACE, AWAY FROM FOODSTUFFS

STORAGE CONDITIONS

: PRODUCT NOT TESTED ON SOILED CONDITIONS

SOILING CONDITIONS

: MICROBIOLOGICS

NEUTRALIZING AGENT

: NEUTRALIZING FLUID

INSTRUCTED BY

SPORE ORIGIN

: SHAUN

LAB NO.

: 949027

RECEIVED ON

: 28/06/2022

DATE ANALYSED

: 29/06/2022

EXPERIMENTAL CONDITIONS:

Obligatory conditions

test organisms:

Bacillus subtilis ATCC 6633

Test temperature:

20°C

Contact time:

60 minutes

Interfering substance:

0.3g/l Bovine serum albumin (Clean conditions)

Test incubation temperature:

30°C

PASS REQUIREMENTS:

The product shall demonstrate at least a 3 decimal log reduction when diluted with hard water/or undiluted and tested under obligatory test conditions. At least one of the test concentrations will demonstrate a log reduction of less than 3 log.



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| Dilution | Vc1 | Vc2 | Average N(wm) | Log N | N ₀ (N/10) | Log No |
|-------------------|---------------|-------------|--------------------|-------|-----------------------|--------|
| 10-4 | 210 | 201 | 2.7 ×106 | C 42 | 2.7 1.05 | F 42 |
| 10-5 | 35 | 30 | -2.7×10^6 | 6.43 | 2.7 x10 ⁵ | 5.43 |
| Is Log Nbetwe | en 6.17 and 6 | .70: Yes | | | | |
| Is Log No between | een 5.17and 5 | .70: Yes | | | | |
| Control of wei | ghted mean co | ounts: 6.32 | | | | |

| Product Concentration | Vc1 | Vc2 | Na (Ave Vc1&Vc2x10) | Log Na | Log Reduction (No: 5.43) |
|--------------------------|------|------|------------------------|--------|--------------------------|
| 25ppm | >300 | >300 | >3000 | >3.48 | <1.95 |
| 250ppm | <15 | <15 | <150 | <2.18 | >3.25 |
| 500ppm | <15 | <15 | <150 | <2.18 | >3.25 |

| Dilutio | on | Vc1 | | Vc2 | | rage vm) | Log N | | N ₀ (N/10) | Lo | g No | |
|--|----------------------------|-------------------------------|--------------------|----------------------------|------------------------|--------------|-----------------|-------------|--------------------------|--------------------------|---------|--|
| 10-4 | | 210 | | 201 | 2.7 | x106 | | | 2.7 x10 ⁵ | 5 | .43 | |
| 10-5 | | 35 6 17 an | d 6.70: Y | 30 | | | 0 21.22 | | | | | |
| | | | id 5.70: Y | | <u>*</u> | | | | | | 1282 | |
| | | | n counts: | | | | | | | | | |
| able 20 Prod | uct | | tion Value | | /c2 | | (Ave 7c2x10) | Log | , Na | | duction | |
| 25pp | | >3 | 300 | > | 300 | | 000 | >3 | .48 | The second second second | .95 | |
| 250n | ppm | < | 15 | < | :15 | < | 150 | <2 | <2.18 | | >3.25 | |
| 250p | | | | | | | | | | | | |
| 500p ALIDAT able 21 | TIONS A | ND CON | ATCC 663 | 33 | ntal | | 150 | | .18 | | .25 | |
| 500p /ALIDAT | ΓΙΟΝS A | ND CON s subtilis | TTROLS ATCC 663 | | ntal ntrol A | | 150 | ntrol B | | >3 | ation C | |
| 500p VALIDAT Table 21 Validati | FIONS A | ND CON | ATCC 663 | 33 Eperimer tions Co | ntal | Neutr | alizer Con | | Metho | od Valida | | |
| 500p ALIDAT Table 21 Validati Vc1 | FIONS A : Bacillu ion susp | ND CON as subtilis ension Ave | ATCC 663 Ex Condi | sperimer tions Co | ntal ntrol A Ave | Neutr Vc1 | ralizer Con | ntrol B Ave | Metho Vc1 | od Valida | Ave | |
| 500p ALIDAT able 21 Validati | FIONS A : Bacillu ion susp | ND CON as subtilis ension Ave | ATCC 663 Ex Condi | sperimer tions Co | ntal ntrol A Ave | Neutr Vc1 | ralizer Con | ntrol B Ave | Metho Vc1 | od Valida | Ave | |
| 500p /ALIDAT Table 21 Validati Vc1 | FIONS A : Bacillu ion susp | ND CON as subtilis ension Ave | ATCC 663 Ex Condi | sperimer tions Co | ntal ntrol A Ave | Neutr Vc1 | ralizer Con | ntrol B Ave | Metho Vc1 | od Valida | Ave | |
| 500p /ALIDAT Table 21 Validati Vc1 | FIONS A : Bacillu ion susp | ND CON as subtilis ension Ave | ATCC 663 Ex Condi | sperimer tions Co | ntal ntrol A Ave | Neutr Vc1 | ralizer Con | ntrol B Ave | Metho Vc1 | od Valida | Ave | |
| 500p ALIDAT Table 21 Validati Vc1 | FIONS A : Bacillu ion susp | ND CON as subtilis ension Ave | ATCC 663 Ex Condi | sperimer tions Co | ntal ntrol A Ave | Neutr Vc1 | ralizer Con | ntrol B Ave | Metho Vc1 | od Valida | Ave | |
| 500p ALIDAT Table 21 Validati Vc1 | FIONS A : Bacillu ion susp | ND CON as subtilis ension Ave | ATCC 663 Ex Condi | sperimer tions Co | ntal ntrol A Ave | Neutr Vc1 | ralizer Con | ntrol B Ave | Metho Vc1 | od Valida | Ave | |
| 500p ALIDAT able 21 Validati | FIONS A : Bacillu ion susp | ND CON as subtilis ension Ave | ATCC 663 Ex Condi | sperimer tions Co | ntal ntrol A Ave | Neutr Vc1 | ralizer Con | ntrol B Ave | Metho Vc1 | od Valida | Ave | |
| 500p /ALIDAT Table 21 Validati Vc1 | FIONS A : Bacillu ion susp | ND CON as subtilis ension Ave | ATCC 663 Ex Condi | sperimer tions Co | ntal ntrol A Ave | Neutr Vc1 | ralizer Con | ntrol B Ave | Metho Vc1 | od Valida | Ave | |
| 500p ALIDAT Table 21 Validati Vc1 | FIONS A : Bacillu ion susp | ND CON as subtilis ension Ave | ATCC 663 Ex Condi | sperimer tions Co | ntal ntrol A Ave | Neutr Vc1 | ralizer Con | ntrol B Ave | Metho Vc1 | od Valida | Ave | |
| 500p ALIDAT able 21 Validati | FIONS A : Bacillu ion susp | ND CON as subtilis ension Ave | ATCC 663 Ex Condi | sperimer tions Co | ntal ntrol A Ave | Neutr Vc1 | ralizer Con | ntrol B Ave | Metho Vc1 | od Valida | Ave | |
| 500p ALIDAT able 21 Validati Vc1 | FIONS A : Bacillu ion susp | ND CON as subtilis ension Ave | ATCC 663 Ex Condi | sperimer tions Co | ntal ntrol A Ave | Neutr Vc1 | ralizer Con | ntrol B Ave | Metho Vc1 | od Valida | Ave | |
| 500p ALIDAT able 21 Validati Vc1 | FIONS A : Bacillu ion susp | ND CON as subtilis ension Ave | ATCC 663 Ex Condi | sperimer tions Co | ntal ntrol A | Neutr Vc1 | ralizer Con | ntrol B Ave | Metho Vc1 | od Valida | Ave | |





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Ref. No: ML-2022-06248

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Certificate/Report

RESULTS REPORTED RELATED ONLY TO ITEMS TESTED

COMPANY NAME

: NANOCARE SA

ADDRESS

: 3 HESKETH ROAD, WESTMEAD, PINETOWN, 3610

SUBJECT

: OUANTITATIVE SUSPENSION TEST FOR THE EVALUATION OF

BACTERICIDAL ACTIVITY OF CHEMICAL DISINFECTANTS FOR INSTRUMENTS USED IN THE MEDICAL AREA SANS

53727:2011 (EN13727:2003): DILUTION- NEUTRALIZATION

MARKED

: NANOCARE/NANOPURE EXP 01/05/2025

ACTIVE INGREDIENT

: 51% NaDCC, 0.016% NANOSILVER

BATCH

: 18901

DILUENT RECOMMENDED

: POTABLE WATER

APPEARANCE

: WHITE TABLETS

DILUENT USED

: STANDARDIZED HARD WATER

CONCENTRATIONS TESTED : 25PPM, 250PPM, 500PPM

APPEARANCE OF DILUTIONS: COLOURLESS, HOMOGENOUS, NO PRECIPITATE OBSERVED

NEUTRALIZING AGENT

: NEUTRALIZING FLUID

SOILING CONDITIONS

: PRODUCT NOT TESTED ON SOILED CONDITIONS

STORAGE CONDITIONS

: STORE IN A COOL DRY PLACE, AWAY FROM FOODSTUFFS

INSTRUCTED BY

: SHAUN

LAB NO.

: 949027

RECEIVED ON

: 28/06/2022

DATE ANALYSED

: 29/06/2022

EXPERIMENTAL CONDITIONS:

Obligatory conditions

test organisms:

Enterococcus hirae ATCC 10541

Pseudomonas aeruginosa ATCC 15442

Staphylococcus aureus ATCC 6538

Test temperature:

20°C

Contact time:

60 minutes

Interfering substance:

0.3g/l Bovine serum albumin (Clean conditions)

Test incubation temperature:

37°C

PASS REQUIREMENTS:

The product shall demonstrate at least a 5 decimal log reduction when diluted with hard water/or undiluted and tested under obligatory test conditions. At least one of the test concentrations will demonstrate a log reduction of less than 5 log.



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RESULTS REPORTED RELATED ONLY TO ITEMS TESTED

TEST VALIDITY

For each test organism:

- N is between 1.5×10^8 and 5.0×10^8 (8.17 $\leq \log N \leq 8.70$)
- N_0 is between 1.5x10⁷ and 5.0x10⁷ (7.17 $\leq \log N \leq 7.70$)
- N_{VO} is between 30 and 160 (3.0x10¹ and 1.6x10²)
- A, B, C are equal to or greater than 0.5xN_{vo}
- Control of weighted mean counts: quotient is not lower than 5 and not higher than 15

RESULTS:

Enterococcus hirae ATCC 10541

Table 22: Nand No values

| Dilution | Vc1 | Vc2 | Average N(wm) | Log N | N ₀ (N/10) | Log No |
|-------------------|---------------|-------------|----------------------|-------|-----------------------|--------|
| 10-6 | 166 | 174 | 0.0-108 | 0.20 | 0.0.107 | 7.00 |
| 10-7 | 25 | 21 | -2.0×10^{8} | 8.30 | 2.0x10 ⁷ | 7.30 |
| Is Log Nbetwe | en 8.17 and 8 | .70: Yes | | | | |
| Is Log No betwe | een 7.17and 7 | .70: Yes | | | | |
| Control of weight | ghted mean co | ounts: 7.39 | | | | |

Table 23: Test Log Reduction Values

| Product Concentration | Vc1 | Vc2 | Na (Ave Vc1&Vc2x10) | Log Na | Log Reduction (No: 7.30) |
|--------------------------|------|------|------------------------|--------|--------------------------|
| 25ppm | >330 | >330 | >3300 | >3.52 | <3.78 |
| 250ppm | <14 | <14 | <140 | <2.15 | >5.15 |
| 500ppm | <14 | <14 | <140 | <2.15 | >5.15 |

Pseudomonas aeruginosa ATCC 15442

Table 24: Nand No values

| Dilution | Vc1 | Vc2 | Average N(wm) | Log N | N ₀ (N/10) | Log No |
|-----------------|---------------|--------------------|---------------------|-------|-----------------------|--------|
| 10-6 | 309 | 296 | 2.7-108 | 8.57 | 0.7-107 | 7 57 |
| 10-7 | 42 | 45 | 3.7x10 ⁸ | 8.37 | 3.7x10 ⁷ | 7.57 |
| Is Log Nbetwe | en 8.17 and 8 | 3.70: Yes | | | - | |
| Is Log No betwo | een 7.17and 7 | 7.70: Yes | | | | |
| Control of wei | ghted mean co | ounts: 6.95 | | | - Altimore | |





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Table 25: Test Log Reduction Values

| Product Concentration | Vc1 | Vc2 | Na (Ave Vc1&Vc2x10) | Log Na | Log Reduction (No:7.57) |
|--------------------------|------|------|------------------------|--------|-------------------------|
| 25ppm | >330 | >330 | >3300 | >3.52 | <4.05 |
| 250ppm | <14 | <14 | <140 | <2.15 | >5.42 |
| 500ррт | <14 | <14 | <140 | <2.15 | >5.42 |

Staphylococcus aureus ATCC 6538

Table 26: Nand No values

| Dilution | Vc1 | Vc2 | Average N(wm) | Log N | N ₀ (N/10) | Log No |
|------------------|----------------|-------------------|-----------------------|-------|-----------------------|--------|
| 10-6 | 255 | 264 | 0.0-108 | 0.40 | 0.0107 | 7.40 |
| 10-7 | 24 | 29 | - 2.6x10 ⁸ | 8.42 | 2.6x10 ⁷ | 7.42 |
| Is Log N between | en 8.17 and 8. | 70: Yes | | 100 | | |
| Is Log No betwe | en 7.17and 7. | 70: Yes | | | | |
| Control of weig | ghted mean co | unts: 9.79 | | | | |

Table 27: Test Log Reduction Values

| Product Concentration | Vc1 | Vc2 | Na (Ave Vc1&Vc2x10) | Log Na | Log Reduction (No:7.42) |
|--------------------------|------|------|------------------------|--------|-------------------------|
| 25ppm | >330 | >330 | >3300 | >3.52 | <3.90 |
| 250ppm | <14 | <14 | <140 | <2.15 | >5.27 |
| 500ppm | <14 | <14 | <140 | <2.15 | >5.27 |

VALIDATIONS AND CONTROLS

Table 28: Enterococcus hirae ATCC 10541

| Valida | tion susp | ension | | perimentions Con | | Neutra | alizer Co | entrol B | Metho | od Valida | tion C |
|----------|-----------|------------|------------|------------------|------------------|--------|-----------|----------|-------|-----------|--------------|
| | | Ave | | | Ave | | | Ave | | | Ave |
| Vc1 | 85 | 00 | Vc1 | 82 | 90 | Vc1 | 74 | | Vc1 | 65 | 60 |
| Vc2 | 91 | - 88 | Vc2 | 78 | 80 | Vc2 | 77 | 75.5 | Vc2 | 73 | 69 |
| 0.5x88 | =44 | | | | | | | | | | |
| Is the N | vo value | between | 30-160: | YES | | | | | | | |
| Is the E | xperimer | ntal Cond | lition A≥0 | 0.5xNvo | value: YI | ES | | | | | |
| Is the N | eutralize | er Conditi | on B≥0.5 | SxNvo va | ılue: YES | | | | | | |
| Is the N | lethod V | alidation | C≥0.5xN | Ivo value | e: YES | | | | | | ************ |

TECHNICAL SIGNATORY



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Table 29: Staphylococcus aureus ATCC 6538

| Valida | tion susp | ension | | perimentions Con | | Neutra | alizer Co | ntrol B | Metho | od Valid | ation C |
|----------|-----------|-----------|-----------|------------------|-----------|--------|-----------|---------|-------|----------|---------|
| | | Ave | | | Ave | | | Ave | | | Ave |
| Vc1 | 112 | 100 | Vc1 | 101 | 00 | Vc1 | 99 | 101 | Vc1 | 92 | 00 F |
| Vc2 | 106 | 109 | Vc2 | 97 | 99 | Vc2 | 103 | 101 | Vc2 | 85 | 88.5 |
| 0.5x10 | 9=54.5 | | | | | | | | | | |
| Is the N | vo value | between | 30-160: | YES | | | | | | | |
| Is the E | xperimer | ital Cond | ition A≥0 | 0.5xNvo | value: YE | S | | | | | |
| Is the N | eutralize | r Conditi | on B≥0.5 | SxNvo va | lue: YES | | 4 | | | | |
| Is the N | Iethod Va | alidation | C≥0.5xN | Ivo value | : YES | | | | | | |

Table 30: Pseudomonas aeruginosa ATCC 15442

| - | tion susp | ension | | tions Con | | Neutra | alizer Co | ntrol B | Metho | od Valid | ation C |
|----------|-----------|-------------------------|-----------------------|--|------------------|-----------|-----------------|------------|-----------|-------------|----------|
| | | Ave | | | Ave | | | Ave | | | Ave |
| Vc1 | 112 | 109 | Vc1 | 101 | 99 | Vc1 | 99 | 101 | Vc1 | 92 | 88.5 |
| Vc2 | 106 | 103 | Vc2 | 97 | 33 | Vc2 | 103 | 101 | Vc2 | 85 | 00.5 |
| | 9=54.5 | | | | | | | | | | |
| | vo value | | | | | | | | | | |
| | - | | | | value: YE | S | | | | | |
| | eutralize | | | | | | w cools | | | | |
| ls the N | 1ethod Va | alidation | C≥0.5xN | Ivo value | : YES | | | | | | |
| | 0: Pseudo | | E | perimen | tal | Neutr | alizer Co | ntrol R | Meth | od Valid | lation C |
| Vallaa | morr susp | Ave | Condi | tions Con | Ave | Mount | anzar co | Ave | AVICTI | ou vano | Ave |
| Vc1 | 96 | Ave | Vc1 | 85 | Ave | Vc1 | 84 | Ave | Vc1 | 61 | AVC |
| | | 99 | | | 89.5 | | | 90 | | | - 63 |
| Vc2 | 102 | | Vc2 | 94 | | Vc2 | 96 | | Vc2 | 65 | |
| 0.5x99 | | | | | | | | | | | 1 |
| | vo value | | | 1010-000-00-00-00-00-00-00-00-00-00-00-0 | | 3,000 | | | | NI WARRANTA | |
| s the E | xperimen | ital Cond | ition A≥0 |).5xNvo | value: YE | S | | | | | |
| s the N | eutralize | r Conditi | on B≥0.5 | xNvo va | lue: YES | | | | | | |
| ls the N | lethod Va | alidation | C≥0.5xN | vo value | : YES | | | | | | |
| Re | ne produc | nts" of SA 999% kill | ANS 5372 (5 log re | 27:2011 duction) | | 27:2003) | standard | (obligate | ory condi | tions) w | hich re |
| | ie mean r | .cauciion | . 01 31X 1C | pricates v | | | | | | | |
| • Th | ie mean r | D 1 | | granica state and | . 1 77 . | 1 | | | | | |
| • Th | | Pseudome | onas aeru | <i>iginosa</i> a | nd <i>Enterc</i> | ococcus h | <i>irae</i> wer | e tested o | nce and | showed | a 5 log |

Conclusion



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RESULTS REPORTED RELATED ONLY TO ITEMS TESTED

COMPANY NAME

: NANOCARE SA

ADDRESS

W: www.bureauveritas.com

: 3 HESKETH ROAD, WESTMEAD, PINETOWN, 3610

SUBJECT

: QUANTITATIVE SUSPENSION TEST FOR THE EVALUATION OF FUNGICIDAL ACTIVITY OF CHEMICAL DISINFECTANTS FOR

INSTRUMENTS USED IN THE MEDICAL AREA SANS 53624:2011

(EN13624:2003): DILUTION-NEUTRALIZATION METHOD

MARKED

: NANOCARE/NANOPURE EXP 01/05/2025

BATCH

: 18901

ACTIVE INGREDIENT

: 51% NaDCC, 0.016% NANOSILVER

DILUENT RECOMMENDED

: POTABLE WATER

APPEARANCE

: WHITE TABLETS

DILUENT USED

: STANDARDIZED HARD WATER

CONCENTRATIONS TESTED : 25PPM, 250PPM & 500PPM

APPEARANCE OF DILUTIONS: COLOURLESS, HOMOGENOUS, NO PRECIPITATE OBSERVED

NEUTRALIZING AGENT

: NEUTRALIZING FLUID

SOILING CONDITIONS

: PRODUCT NOT TESTED ON SOILED CONDITIONS

STORAGE CONDITIONS

: STORE IN A COOL DRY PLACE, AWAY FROM FOODSTUFFS

INSTRUCTED BY

: SHAUN

LAB NO.

: 949027

RECEIVED ON

: 28/06/2022

DATE ANALYSED

: 29/06/2022

EXPERIMENTAL CONDITIONS:

Obligatory conditions

test organisms:

Candida albicans ATCC 10231

Aspergillus brasiliensis ATCC 16404

Test temperature:

20°C

Contact time:

60 minutes

Interfering substance:

0.3g/l Bovine serum albumin (Clean conditions)

Test incubation temperature:

30°C

PASS REQUIREMENTS:

The product shall demonstrate at least a 4 decimal log reduction when diluted with hard water/or undiluted and tested under obligatory test conditions. At least one of the test concentrations will demonstrate a log reduction of less than 4 log.



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RESULTS REPORTED RELATED ONLY TO ITEMS TESTED

TEST VALIDITY

For each test organism:

- *N* is between 1.5×10^7 and 5.0×10^7 ($7.17 \le \log N \le 7.70$)
- N_0 is between 1.5x10⁶ and 5.0x10⁶ (6.17 \le log N \le 6.70)
- N_{VO} is between 30 and 160 (3.0x10¹ and 1.6x10²)
- A, B, C are equal to or greater than 0.5xN_{vo}
- Control of weighted mean counts: quotient is not lower than 5 and not higher than 15

RESULTS:

Candida albicans ATCC 10231

Table 31: Nand No values

| Dilution | Vc1 | Vc2 | Average N(wm) | Log N | N ₀ (N/10) | Log No |
|-------------------|----------------|------------------|-----------------------|-------|-----------------------|--------|
| 10-5 | 226 | 232 | 0.4107 | 7.00 | 0.4-106 | 0.00 |
| 10-6 | 24 | 26 | - 2.4x10 ⁷ | 7.38 | 2.4x10 ⁶ | 6.38 |
| Is Log N between | een 7.17 and 7 | 7.70: Yes | - | | | |
| Is Log No betwe | een 6.17and 6 | .70: Yes | | | | |
| Control of weight | ghted mean co | ounts: 9.16 | | | | |

Table 32: Test Log Reduction Values

| Product Concentration | Vc1 | Vc2 | Na (Ave Vc1&Vc2x10) | Log Na | Log Reduction (No: 6.38) |
|--------------------------|------|------|------------------------|--------|--------------------------|
| 25ppm | >330 | >330 | >3300 | >3.52 | <2.86 |
| 250ppm | <14 | <14 | <140 | <2.15 | >4.23 |
| 500ppm | <14 | <14 | <140 | <2.15 | >4.23 |

Aspergillus brasiliensis ATCC 16404

Table 33: Nand No values

| Dilution | Vc1 | Vc2 | Average N(wm) | Log N | N ₀ (N/10) | Log No |
|-------------------|---------------|-----------------|-----------------------|-------|-----------------------|--------|
| 10-5 | 144 | 139 | 0.0-107 | 7.20 | 0.0106 | 0.20 |
| 10-6 | 24 | 29 | - 2.0x10 ⁷ | 7.30 | 2.0x10 ⁶ | 6.30 |
| Is Log Nbetwe | en 7.17 and 7 | .70: Yes | | | | · · |
| Is Log No betwe | een 6.17and 6 | .70: Yes | | | | |
| Control of weight | ghted mean co | unts: 5.34 | | | | |



LA

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Table 34: Test Log Reduction Values

| Product Concentration | Vc1 | Vc2 | Na (Ave Vc1&Vc2x10) | Log Na | Log Reduction (No: 6.30) |
|--------------------------|------|------|------------------------|--------|--------------------------|
| 25ppm | >165 | >165 | >1650 | >3.22 | <3.08 |
| 250ppm | <14 | <14 | <140 | <2.15 | >4.15 |
| 500ppm | <14 | <14 | <140 | <2.15 | >4.15 |

VALIDATIONS AND CONTROLS

Table 35: Candida albicans ATCC 10231

| Valida | tion susp | ension | | perimentions Co | | Neutra | alizer Co | entrol B | Metho | od Valida | ation C |
|-----------|-----------|------------|----------|-----------------|--|--------|-----------|----------|--------|-----------|---------------------|
| | | Ave | | | Ave | | | Ave | | | Ave |
| Vc1 | 78 | 00 | Vc1 | 76 | 72.5 | Vc1 | 64 | CCF | Vc1 | 62 | C4 |
| Vc2 | 86 | 82 | Vc2 | 69 | 12.5 | Vc2 | 69 | 66.5 | Vc2 | 66 | 64 |
| 0.5x82= | =41 | | | | The state of the s | | | | | 1 | |
| Is the N | vo value | between | 30-160: | YES | | | | | | | 1.72-1 0 |
| Is the Ex | perimen | ıtal Condi | tion A≥0 | .5xNvo | value: YES | 3 | | | 1/ 1/2 | 15.00 | |
| Is the No | eutralize | r Conditio | on B≥0.5 | xNvo va | lue: YES | | | | | | |

Table 36: Aspergillus brasiliensis ATCC 16404

| Product Concentration | V | 7c1 | V | rc2 | Na (Ave Vc1&Vc2x10 | Log | 3 Na | | duction 6.30) |
|--|--|---|---|----------------------------------|---|---------------|------------|-----------|------------------|
| 25ppm | | 165 | | 165 | >1650 | >3 | 3.22 | | .08 |
| 250ppm | | 14 | | 14 | <140 | | .15 | | .15 |
| 500ppm /ALIDATIONS A | | TROLS | | 14 | <140 | | 2.15 | | .15 |
| Table 35: Candid | | | 10231 | ıtal | Neutralizer | Control P | Math | od Valida | tian C |
| Validation susp | | Condi | tions Co | T | Neutranzer | | Meth | oa vanaz | |
| Val 70 | Ave | 17-1 | 7.0 | Ave | Val 04 | Ave | 17 - 4 | 0.0 | Ave |
| Vc1 78 Vc2 86 0.5x82=41 | 82 | Vc1 Vc2 | 76 69 | 72.5 | Vc1 64 Vc2 69 | 66.5 | Vc1 Vc2 | 62 66 | 64 |
| J.UKU4-11 | | | | | | | | | |
| s the Nyo value | hetween | 30~160: | VES | | | | | | |
| s the Nvo value | | | | value: YE S | 3 | | 1000 | | 75-10- |
| Is the Nvo value Is the Experiment Is the Neutralize | tal Cond | ition A≥0 | .5xNvo v | | 3 | | | | |
| s the Experimen s the Neutralize | tal Cond r Conditi | ition A≥0 on B≥0.5 | .5xNvo val | lue: YES | 3 | | | | |
| Is the Experimen | tal Cond r Conditi llidation | ition A≥0 on B≥0.5 C≥0.5xN siliensis A | 2.5xNvo val xNvo value: | lue: YES : YES | Neutralizer (| Control B | Meth | od Valida | tion C |
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Conclusion

- least a 99.99% kill (4 log reduction).
- The mean reduction of six replicates with the limiting test organism *Aspergillus brasiliensis* was 1.9x10⁴. Candida albicans was tested once and showed a 4 log reduction at a lower concentration than Aspergillus brasiliensis.

