

**Evaluation of the bactericidal activity according to the NF EN 13727+A2 : 2015
standard**

Product⁽¹⁾ : **F3320**

Batch⁽¹⁾ : 0224E017220902G

On request of⁽¹⁾:

SODEL
Pôle d'Activités de l'Espérance
190 rue René Barthélémy
F-14140 Lisieux Cedex
France

Loos, 27 September 2022


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Test Manager

The test report includes : **6** pages

I. PRINCIPLE :

The bactericidal activity was determined according to standard NF EN 13727 +A2: "Chemical antiseptics and disinfectants - Quantitative suspension test for the evaluation of bactericidal activity in medicine - Test method and prescriptions (Phase 2, Step 1)" December 2015.

II. SAMPLE(S) IDENTIFICATION :

Name(s)⁽¹⁾: **F3320** – Batch⁽¹⁾: 0224E017220902G – Expiration Date⁽¹⁾ : /

Society⁽¹⁾: **SODEL**

Received at the laboratory: 21 September 2022

Storage conditions at the laboratory⁽¹⁾: Room temperature, in the darkness.

Appearance of the product⁽¹⁾: **Pink liquid.**

Product diluent recommended by the manufacturer⁽¹⁾: Hard water.

Active substance⁽¹⁾ : Chlorhexidine 4%.

III. TEST METHOD AND ITS VALIDATION :

- Neutralization method : Dilution Neutralization.

- Diluent neutralizer : 14 g/L Sodium thiosulfate.

IV. EXPERIMENTAL CONDITIONS :

Period of analysis: from 22 September 2022 to 24 September 2022

Test organism(s): **see table(s) on next page(s).**

Preservation and stock cultures of test organisms following the requirements of the EN 12353 standard.

Diluent used for product test solution: **Hard water at 300 mg/kg of CaCO₃.**

Product test concentration(s): **see table(s) on next page(s).**

Appearance of product dilutions: **Colorless liquid for the concentration 0.1%. Pink liquid for the concentrations 40% and 50%.**

Stability of the test mixture interfering substance / test product(s): **no precipitate.**

Test temperature: **20°C (± 1°C).**

Contact time: **1 minute (± 5 seconds).**

Interfering substance(s): **3g/l bovine albumin with 3mL/L sheep erythrocytes (dirty conditions).**

Incubation temperature: **37°C (± 1°C).**

V. TEST RESULTS

Control and validations of the dilution-neutralization method in the test conditions

(carried out in parallel with tests)

Souche(s) / Strain(s)	Nombre de microorganismes / Enumeration of microorganisms (CFU/ml)				
	Suspension de validation / Validation suspension	Suspension de validation / Validation suspension	Témoign des conditions expérimentales / Experimental conditions control	Témoign de neutralisation / Neutralizer control	Validation de la méthode de neutralisation / Method validation
	Nv₀	Nv_B	A	B	C
<i>Pseudomonas aeruginosa</i> DSM 939	Vc1 : 51 Vc2 : 47 Nv₀ : 49	Vc1 : 55 Vc2 : 52 Nv_B : 5.4 x10 ⁴	Vc1 : 54 Vc2 : 49 A : 51.5	Vc1 : 46 Vc2 : 47 B : 46.5	Vc1 : 52 Vc2 : 59 C : 55.5
<i>Staphylococcus aureus</i> DSM 799	Vc1 : 96 Vc2 : 98 Nv₀ : 97	Vc1 : 85 Vc2 : 96 Nv_B : 9.1 x10 ⁴	Vc1 : 96 Vc2 : 92 A : 94	Vc1 : 95 Vc2 : 90 B : 92.5	Vc1 : 86 Vc2 : 87 C : 86.5
<i>Enterococcus hirae</i> DSM 3320	Vc1 : 75 Vc2 : 78 Nv₀ : 76.5	Vc1 : 85 Vc2 : 76 Nv_B : 8.1 x10 ⁴	Vc1 : 85 Vc2 : 86 A : 85.5	Vc1 : 69 Vc2 : 79 B : 74	Vc1 : 85 Vc2 : 87 C : 86
<i>Escherichia coli</i> K12 DSM 11250	Vc1 : 42 Vc2 : 45 Nv₀ : 43.5	Vc1 : 47 Vc2 : 44 Nv_B : 4.6 x10 ⁴	Vc1 : 41 Vc2 : 42 A : 41.5	Vc1 : 44 Vc2 : 43 B : 43.5	Vc1 : 49 Vc2 : 46 C : 47.5
<p><i>Critères de validation / Validation criteria:</i> <i>Nv₀ entre/between 30 et/and 160 CFU</i> <i>A, B et/ and C ≥ 0.5 x Nv₀</i> <i>B ≥ 0.0005 x Nv_B</i></p> <p style="text-align: right;"><i>Nv_B entre/ between 3.0 x 10⁴ et/and 1.6 x 10⁵</i> <i>C: testé à la concentration maximale / tested at maximum concentration</i></p>					

Conclusion:

The method is **validated** in the test conditions.

Actual test results

Souche(s) / Strain(s)	Suspension d'essai /Test suspension N et/and N ₀	Nombre de microorganismes / Enumeration of microorganisms Na (CFU/mL) à la concentration testée / at the tested concentration (v/v)				
		0.1 %	40 %	50 %		
<i>Pseudomonas aeruginosa</i> DSM 939	10 ⁻⁶ Vc1 : 196 Vc2 : 196 10 ⁻⁷ Vc1 : 16 Vc2 : 18 N = 1.9 x10 ⁸ N ₀ = 1.9 x10 ⁷ log N ₀ = 7.29	10 ⁻⁰ Vc1 : >330 Vc2 : >330 10 ⁻¹ Vc1 : >330 Vc2 : >330 10 ⁻² Vc1 : >330 Vc2 : >330 Na : >3.3 x10 ⁵ log Na : >5.52	10 ⁻⁰ Vc1 : 0 Vc2 : 0 10 ⁻¹ Vc1 : 0 Vc2 : 0 10 ⁻² Vc1 : 0 Vc2 : 0 Na : <1.4 x10 ² log Na : <2.15	10 ⁻⁰ Vc1 : 0 Vc2 : 0 10 ⁻¹ Vc1 : 0 Vc2 : 0 10 ⁻² Vc1 : 0 Vc2 : 0 Na : <1.4 x10 ² log Na : <2.15		
<i>Staphylococcus aureus</i> DSM 799	10 ⁻⁶ Vc1 : >330 Vc2 : >330 10 ⁻⁷ Vc1 : 42 Vc2 : 47 N = 4.5 x10 ⁸ N ₀ = 4.5 x10 ⁷ log N ₀ = 7.65	10 ⁻⁰ Vc1 : >330 Vc2 : >330 10 ⁻¹ Vc1 : >330 Vc2 : >330 10 ⁻² Vc1 : >330 Vc2 : >330 Na : >3.3 x10 ⁵ log Na : >5.52	10 ⁻⁰ Vc1 : 0 Vc2 : 0 10 ⁻¹ Vc1 : 0 Vc2 : 0 10 ⁻² Vc1 : 0 Vc2 : 0 Na : <1.4 x10 ² log Na : <2.15	10 ⁻⁰ Vc1 : 0 Vc2 : 0 10 ⁻¹ Vc1 : 0 Vc2 : 0 10 ⁻² Vc1 : 0 Vc2 : 0 Na : <1.4 x10 ² log Na : <2.15		
<i>Enterococcus hirae</i> DSM 3320	10 ⁻⁶ Vc1 : 242 Vc2 : 214 10 ⁻⁷ Vc1 : 24 Vc2 : 23 N = 2.3 x10 ⁸ N ₀ = 2.3 x10 ⁷ log N ₀ = 7.36	10 ⁻⁰ Vc1 : >330 Vc2 : >330 10 ⁻¹ Vc1 : >330 Vc2 : >330 10 ⁻² Vc1 : >330 Vc2 : >330 Na : >3.3 x10 ⁵ log Na : >5.52	10 ⁻⁰ Vc1 : 0 Vc2 : 0 10 ⁻¹ Vc1 : 0 Vc2 : 0 10 ⁻² Vc1 : 0 Vc2 : 0 Na : <1.4 x10 ² log Na : <2.15	10 ⁻⁰ Vc1 : 0 Vc2 : 0 10 ⁻¹ Vc1 : 0 Vc2 : 0 10 ⁻² Vc1 : 0 Vc2 : 0 Na : <1.4 x10 ² log Na : <2.15		

<i>Escherichia coli</i> K12 DSM 11250	10^{-6} Vc1 : 185 Vc2 : 175 10^{-7} Vc1 : 16 Vc2 : 17 N = 1.8×10^8 N ₀ = 1.8×10^7 log N ₀ = 7.25	10^{-0} Vc1 : >330 Vc2 : >330 10^{-1} Vc1 : >330 Vc2 : >330 10^{-2} Vc1 : >330 Vc2 : >330 Na : $>3.3 \times 10^5$ log Na : >5.52	10^{-0} Vc1 : 0 Vc2 : 0 10^{-1} Vc1 : 0 Vc2 : 0 10^{-2} Vc1 : 0 Vc2 : 0 Na : $<1.4 \times 10^2$ log Na : <2.15	10^{-0} Vc1 : 0 Vc2 : 0 10^{-1} Vc1 : 0 Vc2 : 0 10^{-2} Vc1 : 0 Vc2 : 0 Na : $<1.4 \times 10^2$ log Na : <2.15		
<i>Critères de validation / Validation criteria:</i> N entre/between 1.5×10^8 et/and 5.0×10^8 N ₀ entre/between 1.5×10^7 et/and 5.0×10^7 log N ₀ entre/between 7.17 et/and 7.70						

Reduction (R) of the number of viable cells at the tested concentration (v/v) :

Souche(s) / Strain(s)	0.1 %	40 %	50 %		
<i>Pseudomonas aeruginosa</i> DSM 939	log R : <1.77	log R : >5.14	log R : >5.14		
<i>Staphylococcus aureus</i> DSM 799	log R : <2.13	log R : >5.50	log R : >5.50		
<i>Enterococcus hirae</i> DSM 3320	log R : <1.84	log R : >5.21	log R : >5.21		
<i>Escherichia coli</i> K12 DSM 11250	log R : <1.73	log R : >5.10	log R : >5.10		
<i>Critères d'interprétation/Interpretation criteria:</i> concentration active si /active concentration if log R ≥ 5 concentration non active si /non active concentration if log R < 5					

Number of repetitions : The test was carried out once.

VI. CONCLUSION :

According to the **NF EN 13727+A2 : 2015 standard**, the product

F3320⁽¹⁾

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possesses a bactericidal activity at a concentration of **40%** after **1 minute (± 5 seconds)** at **20°C (± 1°C)** in contact with **3g/l bovine albumin with 3mL/L sheep erythrocytes (dirty conditions)**.

VII. REVISION HISTORY

Date	Revision description	Version
n.a	n.a	n.a

VIII. REMARKS

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