



MINISTERUL SĂNĂTĂȚII AL REPUBLICII MOLDOVA
AGENȚIA NAȚIONALĂ PENTRU SĂNĂTATE PUBLICĂ



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CERTIFICAT
DE ÎNREGISTRARE DE STAT

Nr.	B-0277/2025
din	03.09.2025

I. Denumirea comercială a produsului în Republica Moldova
Dezinfectant "Amigam"

Alte denumiri comerciale

II. Date de identificare ale solicitantului (numele, adresa, țara)
S.R.L. "ECOCHIM-GRUP", Republica Moldova, r-nul Ocnița, or. Otaci, str. Vasilii Voitovici, 21,
7106

III. Date de identificare a producătorului (numele, adresa, țara)
Ecochim – Grup S.R.L., str. Națională 119, Ungheni, Republica Moldova

IV. Date de identificare a produsului

1. Categorie de produs	biocid
1.1. Grupa principală	1
1.2. Tip de produs	1,2

Certificatul de înregistrare este valabil până la data: **03.09.2030.**

În conformitate cu Hotărârea Guvernului nr. 344 din 10.06.2020 s-a decis ca următorul produs biocid poate fi fabricat sau comercializat și utilizat în republica Moldova. Conform prevederilor legislației în vigoare.

Orice modificare a datelor de identificare a produsului biocid, duce în mod automat la anularea certificatului de înregistrare.

Director adjunct

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Date: 2025.09.04 15:53:39 EEST
Reason: MoldSign Signature
Location: Moldova

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Vasile Guștiuc



Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:32:39 EEST
Reason: MoldSign Signature
Location: Moldova

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Anexa 1
la certificatul nr. B-0277/2025 din 03.09.2025 pentru înregistrare de stat a
produsului biocid

I. Denumirea comercială a produsului în Republica Moldova

Dezinfectant "Amigam"

VI. Date privind substanța(e) activă(e) a produsului

<i>Denumirea chimică (IUPAC, ISO sau alte)</i>	<i>Nr. CE</i>	<i>Nr. CAS</i>	<i>Cantitatea în produs</i>
alcool etilic	200-578-6	64-17-5	72-76%
N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine	219-145-8	2372-82-9	0,05%-0,1%

VII. Forma de condiționare

lichid/gel

VIII. Modul de ambalare (tipul, capacitatea)

de la 0,05L până la 1000L.

IX. Domeniul și aria de utilizare

1. Domeniul de utilizare

2. Aria de aplicare

Igiena umană. Dezinfectante și algicide care nu sunt destinate aplicării directe a oameni sau animale.
 Produsul este destinat pentru dezinfectarea mâinilor, suprafețelor, materialelor, echipamentelor și mobilierului.
 Se utilizează în domeniul sanitar (instituții medicale, cabinete, laboratoare), în domeniul industrial, precum și în spații publice și private (birouri, școli, alte instituții).

X. Eficacitate

<i>Activitatea</i>	<i>Metoda de testare/protocolul de testare</i>	<i>Specia/tulpina</i>	<i>Concentrații</i>	<i>Timp de acțiune</i>
Bactericidă în condiții de murdarie	EN 13727:2012+A2:2015	Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli K12, Enterococcus hirae.	80%	60 sec.
Fungicidă în condiții de murdarie	EN 13624:2021	Aspergillus brasilensisi, Candida albicans	80%	60 sec.
Micobacterici dă în condiții de murdarie	EN 14348:2005	Mycobacterium avium, Mycobacterium terrae	80%	60 sec
Virucidă în condiții de murdarie	EN 14476:2013+A2:2019	Poliovirus type1, Adenovirus type 5, Murine Norovirus	80%	60 sec.

XI. Indicații de utilizare

<i>Metoda de aplicare</i>	<i>Concentrația soluției de lucru</i>	<i>Timpul de acțiune</i>
dezinfecția mâinilor prin frecare	nediluat, 3 ml.	60 sec.
prin imersia, înmuiere, irigare, stergere suprafețelor	nediluat	60 sec.

XII. Etichetarea produsului biocid	
Simboluri și indicarea pericolelor	PERICOL.
Fraze de risc (R) și/sau Pictograme de pericol (H)	
Fraze de prudență (S) și/sau Fraze de precauție (P)	

XIII. Categoria de utilizatori
Profesionali, Populație, Industriali,

XIV. Recomandări/restricții privind protecția sănătății și a factorilor de mediu
Utilizare conform instrucțiunii.





Instituto Valenciano de Microbiología

Masía El Romeral
Ctra. Bétera – San Antonio de Benagéber, Km 0,3
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CIF B-96337217

Test with the certificate of GLPs
(Good Laboratory Practices)
No. 2/23-C.VAL. General Directorate of
Pharmacy and Medical Devices of the Health
Department of the Valencian Region. Spain

Quantitative evaluation assay of fungicidal activity in Medicine (phase 2, step1), with the product “Dezinfectant «Amigam»”. (EN 13624 : 2021 Standard)

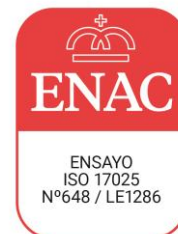
Report

Registration No.: D/25/B0243.

- | | |
|---|---|
| 1. Identification of the laboratory | Instituto Valenciano de Microbiología. |
| 2. Client identification | Ecochim-Grup S.R.L. |
| Address | Republic of Moldava, Ungheni city,
str.Nationala 119 |
| 3. Sample identification (information provided by the client) | |
| • Product name | Dezinfectant «Amigam». |
| • Batch number | 14062028. |
| • Expiration date | 2028-06-14. |
| • Manufacturer / supplier | Ecochim-Grup S.R.L. |
| • Storing conditions | Not indicated. |
| • Conditions of use | Hygienic handrub, surgical handrub,
instruments disinfection, surface
disinfection. |
| • Diluent recommended by the manufacturer | Not indicated. |
| • Active(s) Substance(s) and its concentration
(s) | Ethyl alcohol 72%, CAS: 64-17-5 and CE
200-578-6, N-(3-Aminopropyl)-N-
dodecylpropane-1,3-diamine 0.05%, CAS
No.: 2372-82-9 EC-No.: 219-145-8. |
| • Concentrations ordered for the assay | Ready to use. |

IVAMI is not responsible for client-supplied information. This information is **not covered** by the ENAC accreditation.

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Date: 2025.10.21 09:32:43 EEST
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Location: Moldova
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4. Information about sample reception

- Date of reception of the sample 2025/03/26.
- Date of reception of order with test conditions 2025/03/25.
- Aspect of the received sample Colourless transparent liquid in plastic container.

5. Method of assay and its validation (EN 13624: 2021 Standard)

- Method used Dilution-neutralization.
- Neutralizer Tryptone 5 g/L, yeast extract 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulphite 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.

6. Experimental conditions

- Assay period (including prior preparation of the strains) 2025/04/30 to 2025/05/10.
- Solvent of the product used in the assay Sterile distilled water.
- Product concentrations for the assay Pure (80%), 50% and 0.1%.
- Aspect of the dilutions of the product Transparent liquid.
- Contact time 60 seconds.
- Assay temperature $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$.
- Interfering substance Bovine serum albumin 3 g/L plus erythrocytes 3 mL/L.
- Stability of the mixture (interfering substance and product in sterile distilled water)..... 80%: floc formation. 50% and 0.1%: stable.
- Temperature of incubation $+30^{\circ}\text{C} \pm 1^{\circ}\text{C}$.
- Identification of the strain used:
 - *Aspergillus brasiliensis* (CECT 2574 = ATCC 16404).
 - *Candida albicans* (CECT 1394 = ATCC 10231).

7. Results of the assay

- Assay of validation See tables 1, 2, 4 and 5.
- Evaluation of fungicidal activity See tables 3 and 6.
- Number of replicates per assay organism 1.

8. Special remarks

- All controls and validation were between the basic limits.
- For a valid test, at least one concentration must show a log reduction lower than 4 log and at least one concentration must show a log reduction equal or higher than 4 log.
- Small precipitates are observed during the test procedure at the 80% concentration. The counting of microorganisms occluded inside a precipitate is difficult and can be altered. During the test carried out at the mentioned concentration, no microbiological growth was observed.
- The maximum concentration that can be tested is 80% due to the mixtures made during the test.

9. Conclusion

The product **Dezinfectant «Amigam»**, batch 14062028, when it is pure (80%), concentration requested by the client, **shows fungicidal activity**, after 60 seconds at 20°C $\pm 1^\circ\text{C}$, under dirty conditions (bovine serum albumin 3 g/L plus erythrocytes 3 mL/L), for the reference strains *Aspergillus brasiliensis* (CECT 2574 = ATCC 16404) and *Candida albicans* (CECT 1394 = ATCC 10231), when tested as required by the **EN 13624: 2021 Standard**.

Note: The results obtained correspond to the sample received in the laboratory.

Use of the ENAC mark: The ENAC “mark” can only be used by the holder of the accreditation. Its use in packaging, installations, shop windows, advertising or other documentation format other than that issued by the accredited entity (IVAMI) is not allowed.

Bétera (Valencia), May 14, 2025.

MORENO ZARAGOZA,
PILAR (FIRMA)

Fdo. Pilar Moreno.
Responsible Technician
(Investigator)

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials and reagents, following as well the Good Laboratory Practices (GLPs) and the final report contains the primary data obtained.

**MONTOYA VIECO,
ELENA (FIRMA)**

Signed. Elena Montoya.
Responsible for the Laboratory Area
(Study Director)

**ESTEBAN BERMUDEZ,
ENCARNACION PILAR
(FIRMA)**

Signed. Encarnación Esteban.
Technical Director
(Quality Assurance Director)

Reference

- **EN 13624: 2021.** Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of the fungicidal or yeasticidal activity in the medical area. Test method and requirements (phase 2, step 1).

Results of the assay with *Aspergillus brasiliensis* (CECT 2574 = ATCC 16404).

Method: Dilution-neutralization; Seeding: Pour plate; No. of plates: 4/mL.

Table 1.-Validation and controls.

Suspension of validation (N_{v0})			Control of experimental (A)			Control of the neutralizer (B)			Validation of the method (C) Sample concentration: 80%		
V_{C1}	48	$X=$	V_{C1}	43	$X=$	V_{C1}	52	$X=$	V_{C1}	45	$X=$
V_{C2}	50	49	V_{C2}	45	44	V_{C2}	46	49	V_{C2}	48	46.5
$30 \leq X \text{ of } N_{v0} \leq 160?$ Yes			$X \text{ of } A \text{ is } \geq 0.5x$ $X \text{ if } N_{v0}? \text{ Yes}$			$X \text{ of } B \text{ is } \geq 0,5 \times X \text{ of } N_{v0}, \text{ or } N_{vB}/1000?$ Yes			$X \text{ of } C \text{ is } \geq 0.5x$ $X \text{ of } N_{v0}? \text{ Yes}$		
Suspension of validation (N_{vB})			$V_{C1}: 54 \quad V_{C2}: 56$			$X = 55$ $30 \leq x \text{ of } N_{vB}/1000 \leq 160? \text{ Yes}$					

Table 2.-Suspension of the assay.

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.56 \times 10^7$
	10^{-5}	150	156	$\lg N = 7.19$ $N_0 = N/10$
	10^{-6}	17	20	$\lg N_0 = 6.19$ $6.17 \leq \lg N_0 \leq 6.70? \text{ Yes}$

Table 3.- Results of the activity test with the sample.

Concentrations of the sample (%)	Dilution steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 6.19$)	Time of contact (seconds)
80%	Na^0	<14	<14	<2.15	>4.04	60
	Na^{-1}	<14	<14			
50%	Na^0	51	53	2.72	3.47	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>660	>660	>4.82	<1.37	60
	Na^{-1}	>660	>660			

Counts per plate:

(N) $10^{-5} = 37 + 39 + 40 + 34; 43 + 33 + 41 + 39;$
 $10^{-6} = 5 + 3 + 4 + 5; 4 + 5 + 5 + 6;$

Sample:

80% = $Na^0 = 0 + 0 + 0 + 0; 0 + 0 + 0 + 0;$

$Na^{-1} = 0 + 0 + 0 + 0; 0 + 0 + 0 + 0;$

50% = $Na^0 = 12 + 16 + 12 + 11; 15 + 14 + 13;$

$Na^{-1} = 2 + 1 + 3 + 2; 1 + 1 + 4 + 3;$

0.1 % = $Na^0 = >165 + >165 + >165 + >165; >165 + >165 + >165 + >165;$

$Na^{-1} = >165 + >165 + >165 + >165; >165 + >165 + >165 + >165.$

A = $13 + 6 + 14 + 10; 9 + 15 + 11 + 10;$

B = $14 + 16 + 9 + 13; 12 + 11 + 10 + 13;$

C = $12 + 15 + 8 + 10; 15 + 11 + 10 + 12;$

N_{V0} = $13 + 12 + 11 + 12; 14 + 10 + 13 + 13;$

N_{VB} = $12 + 15 + 13 + 14; 15 + 16 + 13 + 12;$

Results of the assay with *Candida albicans* (CECT 1394 = ATCC 10231).

Method: Dilution-neutralization; Seeding: Pour plate; No. of plates: 1/mL.

Table 4.-Validation and controls.

Suspension of validation (N_{v0})			Control of experimental (A)			Control of the neutralizer (B)			Validation of the method (C) Sample concentration: 80%		
V_{C1}	53	$X=$	V_{C1}	48	$X=$	V_{C1}	57	$X=$	V_{C1}	49	$X=$
V_{C2}	58	55.5	V_{C2}	46	47	V_{C2}	56	56.5	V_{C2}	46	47.5
$30 \leq X \text{ of } N_{v0} \leq 160?$ Yes			$X \text{ of A is } \geq 0.5x$ $X \text{ if } N_{v0}? \text{ Yes}$			$X \text{ of B is } \geq 0,5 \times X \text{ of } N_{v0}, \text{ or } N_{vB}/1000?$ Yes			$X \text{ of C is } \geq 0.5x$ $X \text{ of } N_{v0}? \text{ Yes}$		
Suspension of validation (N_{vB})			$V_{C1}: 60 \quad V_{C2}: 65$			$X = 62.5$ $30 \leq x \text{ of } N_{vB}/1000 \leq 160? \text{ Yes}$					

Table 5.-Suspension of the assay.

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.71 \times 10^7$
	10^{-5}	166	167	$\lg N = 7.23$ $N_0 = N/10$
	10^{-6}	20	23	$\lg N_0 = 6.23$ $6.17 \leq \lg N_0 \leq 6.70? \text{ Yes}$

Table 6.- Results of the activity test with the sample.

Sample concentration (%)	Dilution step	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ or } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 6.23$)	Time of contact (seconds)
80%	Na^0	<14	<14	<2.15	>4.08	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>4.08	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<1.71	60
	Na^{-1}	>330	>330			



Instituto Valenciano de Microbiología

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Test with the certificate of GLPs
(Good Laboratory Practices)
No. 2/23-C.VAL. General Directorate of
Pharmacy and Medical Devices of the Health
Department of the Valencian Region. Spain

Quantitative evaluation assay of the bactericidal activity in the medical area (phase 2, step 1), with the product “Dezinfectant «Amigam»”. (EN 13727: 2012 + A2: 2015 Standard)

Report

Registration No. : D/25/B0242.

1. **Laboratory identification** Instituto Valenciano de Microbiología.
2. **Client identification** Ecochim-Grup S.R.L.
Address Republic of Moldava, Ungheni city,
str.Nationala 119
3. **Sample identification** (information provided by the client)
 - Product name **Dezinfectant «Amigam».**
 - Batch number 14062028.
 - Expiration date 2028-06-14.
 - Manufacturer /supplier Ecochim-Grup S.R.L.
 - Store conditions Not indicated.
 - Conditions of use Hygienic handrub, surgical handrub,
instruments disinfection, surface disinfection.
 - Solvent of the product recommended by the
manufacturer Not indicated.
 - Active(s) Substance(s) and its
concentration (s) Ethyl alcohol 72%, CAS: 64-17-5 and CE 200-
578-6, N-(3-Aminopropyl)-N-
dodecylpropane-1,3-diamine 0.05%, CAS
No.: 2372-82-9 EC-No.: 219-145-8.
 - Concentrations ordered for the assay Ready to use.

IVAMI is not responsible for client-supplied information. This information **is not covered**
by the ENAC accreditation.

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Location: Moldova

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4. Information about sample reception

- Date of reception of the sample 2025/03/26.
- Date of reception of order with test conditions 2025/03/25.
- Aspect of the received sample..... Colourless transparent liquid in plastic container.

5. Method of assay and its validation (EN 13727: 2012 + A2: 2015 Standard)

- Method used Dilution-neutralization.
- Neutralizer Tryptone 10 g/L, yeast extract 5 g/L, dextrose 20 g/L, sodium thioglycolate 2 g/L, sodium thiosulfate 2 g/L, sodium bisulphite 5 g/L, soya lecithin 14 g/L, polysorbate-80 10 g/L, glycine 2 g/L, l-histidine 2 g/L and saponin 60 g/L.

6. Experimental conditions

- Assay period (including prior preparation of the strains)..... 2025/05/05 to 2025/05/09.
- Solvent of the product used in the assay..... Sterile distilled water.
- Product concentrations for the assay Pure (80%), 50% and 0.1%.
- Aspect of the dilutions of the product Transparent liquid.
- Contact time 60 seconds.
- Assay temperature $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$.
- Interfering substance Bovine serum albumin 3 g/L plus erythrocytes 3 mL/L.
- Stability of the mixture (interfering substance and product diluted in sterile distilled water) 80%: floc formation. 50% and 0.1%: stable.
- Incubation temperature $+36^{\circ}\text{C} \pm 1^{\circ}\text{C}$.
- Identification of the strains used:
 - *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442).
 - *Staphylococcus aureus* (CECT 239 = ATCC 6538).
 - *Enterococcus hirae* (CECT 4081 = ATCC 10541).
 - *Escherichia coli* K12 (CECT 433 = NCTC 10538).

7. Results of the assay

- Assay of validation See tables 1, 2, 4, 5, 7, 8, 10 and 11.
- Evaluation of bactericidal activity See tables 3, 6, 9 and 12.
- Number of replicates per assay organism. 1.

8. Special remarks

- All controls and validation were between the basic limits.
- For a valid test, at least one concentration must show a log reduction lower than 5 log, and at least one concentration must show a log reduction equal or higher than 5 log.
- Small precipitates are observed during the test procedure at the 80% concentration. The counting of microorganisms occluded inside a precipitate is difficult and can be altered. During the test carried out at the mentioned concentration, no microbiological growth was observed.
- The maximum concentration that can be tested is 80% due to the mixtures made during the test.

9. Conclusion

The product **Dezinfectant «Amigam»**, batch 14062028, when it is pure (80), concentration requested by the client, **shows bactericidal activity** after 60 seconds at $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, under dirty conditions (bovine serum albumin 3 g/L plus erythrocytes 3 mL/L), for the reference strains *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442), *Staphylococcus aureus* (CECT 239 = ATCC 6538), *Enterococcus hirae* (CECT 4081 = ATCC 10541) and *Escherichia coli* K12 (CECT 433 = NCTC 10538), when tested according to **EN 13727: 2012 + A2: 2015 Standard**.

Note: The results obtained correspond to the sample received in the laboratory.

Use of the ENAC mark: The ENAC “mark” can only be used by the holder of the accreditation. Its use in packaging, installations, shop windows, advertising, or other documentation format other than that issued by the accredited entity (IVAMI) is not allowed.

Bétera (Valencia), May 14, 2025.

MORENO ZARAGOZA,
PILAR (FIRMA)

Signed. Pilar Moreno
Responsible Technician
(Investigator)

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials, and reagents, following the Good Laboratory Practices (GLPs) as well and the final report contains the primary data obtained.

**MONTOYA VIECO,
ELENA (FIRMA)**

Signed. Elena Montoya.
Responsible for the Laboratory Area
(Study Director)

**ESTEBAN BERMUDEZ,
ENCARNACION PILAR
(FIRMA)**

Signed. Encarnación Esteban.
Technical Director
(Quality Assurance Director)

Reference

- **EN 13727: 2012 + A2: 2015.** Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in Medicine. Test method and requirements (phase 2, step 1).

Results of the assay (Bactericidal suspension) with *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 1.-Validation and controls

Suspension of validation (N_{v0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 80%		
V_{c1}	44	$X=$	V_{c1}	39	$X=$	V_{c1}	43	$X=$	V_{c1}	40	$X=$
V_{c2}	45	44.5	V_{c2}	39	39	V_{c2}	40	41.5	V_{c2}	36	38
$30 \leq X \text{ of } N_{v0} \leq 160?$ Yes			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{v0}?$ Yes			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{v0}?$ Yes			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{v0}?$ Yes		
Suspension of validation (N_{vB})			V_{c1} : 50 V_{c2} : 56			$X = 53$ $30 \leq X \text{ of } N_{vB}/1000 \leq 160?$ Yes					

Table 2.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{c1}	V_{c2}	$X_{wm} = 2.18 \times 10^8$, $\lg N = 8.34$ $N_0 = N/10$; $\lg N_0 = 7.34$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	208	210	
	10^{-7}	30	32	

Table 3.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{c1}	V_{c2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.34$)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.19	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.19	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.82	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{c1} and V_{c2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

Results of the assay (Bactericidal suspension) with *Staphylococcus aureus* (CECT 239 = ATCC 6538).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 4.-Validation and controls

Suspension of validation (N_{v0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 80%		
V_{c1}	48	$X=$	V_{c1}	35	$X=$	V_{c1}	53	$X=$	V_{c1}	43	$X=$
V_{c2}	46	47	V_{c2}	36	35.5	V_{c2}	57	55	V_{c2}	39	41
$30 \leq X \text{ of } N_{v0} \leq 160?$ Yes			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{v0}?$ Yes			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{v0}?$ Yes			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{v0}?$ Yes		
Suspension of validation (N_{vB})			V_{c1} : 75 V_{c2} : 76			$X = 75.5$ $30 \leq X \text{ of } N_{vB}/1000 \leq 160?$ Yes					

Table 5.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{c1}	V_{c2}	$X_{wm} = 2.48 \times 10^8$, $\lg N = 8.39$ $N_0 = N/10$; $\lg N_0 = 7.39$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	248	242	
	10^{-7}	29	27	

Table 6.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{c1}	V_{c2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.39$)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.24	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.24	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.87	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{c1} and V_{c2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

Results of the assay (Bactericidal suspension) with *Enterococcus hirae* (CECT 4081 = ATCC 10541).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 7.-Validation and controls

Suspension of validation (N_{v0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 80%		
V_{c1}	55	$X=$	V_{c1}	49	$X=$	V_{c1}	57	$X= 58$	V_{c1}	51	$X=$
V_{c2}	50	52.5	V_{c2}	41	45	V_{c2}	59		V_{c2}	47	49
$30 \leq X \text{ of } N_{v0} \leq 160?$ Yes			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{v0}?$ Yes			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{v0}?$ Yes			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{v0}?$ Yes		
Suspension of validation (N_{vB})			V_{c1} : 61 V_{c2} : 63			$X = 62$ $30 \leq X \text{ of } N_{vB}/1000 \leq 160?$ Yes					

Table 8.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{c1}	V_{c2}	$X_{wm} = 2.23 \times 10^8$, $\lg N = 8.35$ $N_0 = N/10$; $\lg N_0 = 7.35$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	224	219	
	10^{-7}	27	21	

Table 9.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{c1}	V_{c2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0=7.35$)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.20	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.20	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.83	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{c1} and V_{c2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

Results of the assay (Bactericidal suspension) with *Escherichia coli* K12 (CECT 433 = NCTC 10538).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 10.-Validation and controls

Suspension of validation (N_{v0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 80%		
V_{c1}	42	$X=$	V_{c1}	41	$X=$	V_{c1}	46	$X=$	V_{c1}	45	$X=$
V_{c2}	48	45	V_{c2}	46	43.5	V_{c2}	48	47	V_{c2}	38	41.5
$30 \leq X \text{ of } N_{v0} \leq 160?$ Yes			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{v0}?$ Yes			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{v0}?$ Yes			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{v0}?$ Yes		
Suspension of validation (N_{vB})			V_{c1} : 50 V_{c2} : 53			$X = 51.5$ $30 \leq X \text{ of } N_{vB}/1000 \leq 160?$ Yes					

Table 11.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{c1}	V_{c2}	$X_{wm} = 1.79 \times 10^8$, $\lg N = 8.25$ $N_0 = N/10$; $\lg N_0 = 7.25$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	167	181	
	10^{-7}	22	24	

Table 12.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{c1}	V_{c2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0=7.25$)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.10	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.10	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.73	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{c1} and V_{c2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).



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Test with the certificate of GLPs
(Good Laboratory Practices)
No. 2/23-C.VAL. General Directorate of
Pharmacy and Medical Devices of the Health
Department of the Valencian Region. Spain

Quantitative suspension test for the evaluation of virucidal activity in the medical area(phase 2, step 1), against Poliovirus type 1, Adenovirus type 5 and Murine Norovirus with the product “Dezinfectant «Amigam»” (EN 14476: 2013 + A2: 2019 Standard)

Report

Registration No.: D/25/V090.

1. **Laboratory identification** Instituto Valenciano de Microbiología.
2. **Client identification** Ecochim-Grup S.R.L.
Address Republic of Moldova, Ungheni city, str.
Nationala 119, MD-3603.
3. **Sample identification** (information provided by the client)
 - Product name **Dezinfectant «Amigam».**
 - Batch number 14062028.
 - Expiration date 2028/06/14.
 - Manufacturer /supplier Ecochim-Grup S.R.L.
 - Store conditions Not indicated.
 - Conditions of use Hygienic handrub, instruments disinfection and surface disinfection.
 - Diluent of the product recommended by the manufacturer Not indicated.
 - Active(s) Substance(s) and its concentration (s) Ethyl alcohol 72% CAS : 64-17-5 and CE 200-578-6, N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine 0.05%, CAS No. : 2372-82-9 EC-No. : 219-145-8.
 - Concentrations ordered for the assay 80% (Ready to use).

IVAMI is not responsible for client-supplied information. This information **is not covered** by the ENAC accreditation.

Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:32:22 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ



DESIN-1078-b / EN 14476: 2013 + A2: 2019

Registration No.: D/25/V090

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Instituto Valenciano de Microbiología

4. Information about sample reception

- Date of reception of the sample 2025/03/26.
- Date of reception of order with test conditions 2025/03/26.
- Aspect of the received sample Colourless transparent liquid in plastic container with identification label.

5. Testing method

Procedure **DESIN-1078** (EN 14476: 2013 + A2: 2019 Standard).

6. Experimental conditions

- Assay period 2025/04/01 to 2025/04/17.
- Titration method TCID₅₀
(Tissue Culture Infective Dose 50%).
- Incubation temperature 37°C ±1°C.
- Product concentrations for the assay 80%, 50% and 0.1%.
- Contact time 60 seconds.
- Contact temperature 20°C ±1°C.
- Procedure to stop product cytotoxicity . Molecular sieving (< 4 columns).
- Procedure to stop product activity Cooling with ice.
- Solvent of the product used in the assay Sterile distilled water.
- Aspect of the dilutions of the product ... Transparent.
- Stability of the mixture (product with solvent and interfering substance)..... Stable.
- Interfering substance:
 - Dirty conditions in the presence of bovine serum albumin 3 g/L and erythrocytes 3 mL/L.
- Identification of the origin of viral strains and number of passages Poliovirus type 1 (ATCC VR-192)
aliquot: 2024/11/11 passage 2.
Adenovirus type 5(ATCC VR-5)
aliquot: 2024/04/26 passage 2.
Murine Norovirus (strain S99 Berlin)
aliquot: 2024/08/01 passage 2.
- Cell lines (name, origin, number of Passages and cell culture medium) ... Vero, ref: FTVE, working aliquot 11, passage 18 and working aliquot 12, passage 10.

Raw 264.7, Public Health England, working aliquot 11, passages 17 and working aliquot 12, passage 10.

7. Validation of assay results

Titre of the viral suspension and cytotoxicity control

Poliovirus type 1 (ATCC VR-192)	log TCID₅₀
• Titre of the viral suspension for the control virus with a 95% confidence interval at the requested test time and under the requested test conditions.	6.99 ± 0.41
• Cytotoxicity level with the highest test concentration	0.50
• Maximum detectable viral inactivation (difference between the titer of the viral suspension at the requested test time and the level of cytotoxicity)	6.49
Adenovirus type 5 (ATCC VR-5)	log TCID₅₀
• Titre of the viral suspension for the control virus with a 95% confidence interval at the requested test time and under the requested test conditions.	6.57 ± 0.43
• Cytotoxicity level with the highest test concentration	0.50
• Maximum detectable viral inactivation (difference between the titer of the viral suspension at the requested test time and the level of cytotoxicity)	6.07
Murine Norovirus (strain S99 Berlin)	log TCID₅₀
• Titre of the viral suspension for the control virus with a 95% confidence interval at the requested test time and under the requested test conditions.	8.08 ± 0.34
• Cytotoxicity level with the highest test concentration	0.50
• Maximum detectable viral inactivation (difference between the titer of the viral suspension at the requested test time and the level of cytotoxicity)	7.58

Note: The titre of the test suspension must be sufficiently high to at least enable a titre reduction of 4 log₁₀. The cytotoxicity of the test solution of the product must not affect the cell morphology, growth or susceptibility of the cells for the test virus in the dilutions of the test mixture which are necessary to demonstrate at least 4 log₁₀ reduction in the virus titer.

Interference control – control of cell susceptibility

Poliovirus type 1 (ATCC VR-192)	log TCID₅₀
• Titre of the viral suspension with cells not treated by the test solution with the test sample	7.41
• Titre of the viral suspension with cells treated by the test solution with the test sample	6.91
• Log difference between viral titres using cells treated and untreated with the test sample	0.50
Adenovirus type 5 (ATCC VR-5)	log TCID₅₀
• Titre of the viral suspension with cells not treated by the test solution with the test sample	7.49
• Titre of the viral suspension with cells treated by the test solution with the test sample	6.91
• Log difference between viral titres using cells treated and untreated with the test sample	0.58
Murine Norovirus (strain S99 Berlin)	log TCID₅₀
• Titre of the viral suspension with cells not treated by the test solution with the test sample	8.82
• Titre of the viral suspension with cells treated by the test solution with the test sample	8.16
• Log difference between viral titres using cells treated and untreated with the test sample	0.66

Note: The difference in decimal logs between the virus titre in untreated cells and cells treated with the test suspension with the test sample must be $< 1 \log_{10}$.

Control of efficiency of suppression of product's activity

Poliovirus type 1 (ATCC VR-192)	log TCID₅₀
• Titre of the viral suspension after 30 minutes of incubation in an ice bath, without contact of the virus with the test sample	6.82
• Titre of the viral suspension by exposing the virus to the test sample and incubation for 30 minutes in an ice bath	6.58
• Logarithmic difference between viral titres of the unexposed virus and virus exposed to the test suspension	0.24
Adenovirus type 5 (ATCC VR-5)	log TCID₅₀
• Titre of the viral suspension after 30 minutes of incubation in an ice bath, without contact of the virus with the test sample	6.75
• Titre of the viral suspension by exposing the virus to the test sample and incubation for 30 minutes in an ice bath	6.49
• Logarithmic difference between viral titres of the unexposed virus and virus exposed to the test suspension	0.26
Murine Norovirus (strain S99 Berlin)	log TCID₅₀
• Titre of the viral suspension after 30 minutes of incubation in an ice bath, without contact of the virus with the test sample	7.82
• Titre of the viral suspension by exposing the virus to the test sample and incubation for 30 minutes in an ice bath	7.50
• Logarithmic difference between viral titres of the unexposed virus and virus exposed to the test suspension	0.32

Note: The difference in decimal logarithms between the virus titre without exposure to the test sample and exposed to the test sample must be $\leq 0.5 \log_{10}$.

Reference test for virus inactivation(formaldehyde 1.4%)

Poliovirus type 1 (ATCC VR-192)	log TCID₅₀	
• Cytotoxicity level of formaldehyde at 0.7% (w:v)	0.5	
• Viral quantification of virus control in the reference test	0 min	6.91
	60 min	6.66
• Viral quantification in the reference test	30 min	4.74
	60 min	3.41
• Reduction obtained in the reference test	30 min	1.92
	60 min	3.25
Adenovirus type 5 (ATCC VR-5)	log TCID₅₀	
• Cytotoxicity level of formaldehyde at 0.7% (w:v)	0.5	
• Viral quantification of virus control in the reference test	0 min	6.66
	60 min	6.49
• Viral quantification in the reference test	30 min	2.91
	60 min	2.33
• Reduction obtained in the reference test	30 min	3.58
	60 min	4.16
Murine Norovirus (strain S99 Berlin)	log TCID₅₀	
• Cytotoxicity level of formaldehyde at 0.7% (w:v)	0.5	
• Viral quantification of virus control in the reference test	0 min	7.66
	60 min	7.49
• Viral quantification in the reference test	30 min	5.07
	60 min	3.83
• Reduction obtained in the reference test	30 min	2.42
	60 min	3.66

Note: The difference in decimal logs between the titer of the virus control in the reference inactivation test and the titer of formaldehyde-treated virus must be between 0.5 and 2.5 log₁₀ after 30 minutes and between 2 and 4.5 log₁₀ after 60 minutes for Poliovirus type 1; between 3 and 5 log₁₀ after 30 minutes and between 3.5 and 5.5 log₁₀ after 60 minutes for Adenovirus type 5; and between 1 and 3 log₁₀ after 30 minutes and between 2 and 4 log₁₀ after 60 minutes for murine Norovirus.

8. Special remarks

- All controls and validation were between the basic limits.
- To be accepted the assay, at least one concentration of the product must show a log reduction equal or higher than 4 log, and at least one concentration must show a log reduction lower than 4 log.

9. Assay results

9.1 Description of the results under the requested test conditions

Virus of assay	Test concentrations, reduction obtained with the confidence interval of 95% and virucidal activity		
	80%	50%	0.1%
Poliovirus type 1	4.74 ± 0.57 TCID ₅₀ Shows	1.83 ± 0.61 TCID ₅₀ Does not show	0.00 ± 0.58 TCID ₅₀ Does not show
Adenovirus type 5	5.25 ± 0.57 TCID ₅₀ Shows	4.16 ± 0.55 TCID ₅₀ Does not show a conclusive result	0.00± 0.61 TCID ₅₀ Does not show
Murine Norovirus	≥7.58 ± 0.34 TCID ₅₀ Shows	5.26 ± 0.53 TCID ₅₀ Shows	0.09 ± 0.53 TCID ₅₀ Does not show

Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.
TCID₅₀: Tissue Culture Infectious Dose 50%.

9.2 Tables of results and graphics

See tables 1 to 6 and figures 1 to 3.

10. Conclusion

The product “**Dezinfectant «Amigam»**”, batch 14062028, at the concentration of **80%**, in dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), requested by the client, and with a contact time of 60 seconds and 20°C of temperature, **shows** virucidal activity against Poliovirus type 1 (ATCC VR-192), Adenovirus type 5 (ATCC VR-5) and Murine Norovirus (strain S99 Berlin), when the activity is evaluated in accordance with **EN 14476: 2013 + A2: 2019** Standard.

Therefore, the tested product “**Dezinfectant «Amigam»**”, batch 14062028, **shows general virucidal activity**, at the concentrations of **80%**, when the activity is evaluated in accordance with **EN 14476: 2013 + A2: 2019** Standard.

Note 1: The results obtained correspond to the sample received in this laboratory.

Note 2: The information that depend on the information received from the client and are not facilitated by the same one, shown as "not indicated".

Use of the ENAC mark: The ENAC “mark” can only be used by the holder of the accreditation. Its use in packaging, installations, shop windows, advertising or other documentation format other than that issued by the accredited entity (IVAMI) is not allowed.

Bétera (Valencia), April 22, 2025.

Signed. Noelia Ros.
Responsible Technician
(Investigator)

ROS ESTELLES,
NOELIA (FIRMA)

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials and reagents, following as well the Good Laboratory Practices (GLPs) and the final report contains the primary data obtained.

FERNANDEZ FUENTES,
MIGUEL ANGEL (FIRMA)

Signed. Miguel Ángel Fernández.
Responsible for the Laboratory Area
(Study Director)

Signed. Encarnación Esteban.
Technical Director
(Quality Assurance Director)

Reference

- **EN 14476: 2013 + A2: 2019 Standard.** Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of virucidal activity in the medical area. Test method and requirements (phase 2/step1).

Table 1. Results of activity of the test sample with Poliovirus type 1 (ATCC VR-192) under test conditions requested by the client.

Assay	Concentration	log ₁₀ TCID ₅₀ after...				Reduction with the confidence interval of 95 %
		0 min	60 sec	30 min	60 min	
Test sample	80%	-	2.25	-	-	4.74 ± 0.57
	50%	-	5.16	-	-	1.83 ± 0.61
	0.1%	-	6.99	-	-	0.00 ± 0.58
Virus control	NA	6.99	6.99	-	-	NA
NA: not applicable; Times indicated by Standard for surface disinfection: maximum 5 or 60 min Times indicated by Standard for instrument disinfection: maximum 60 min Times indicated by Standard for textile disinfection: maximum 60 min Times indicated by Standard for hygienic hand treatment by friction and hygienic hand washing: between 30 and 120 seconds. Viricidal activity exists when the virus titer shows a reduction ≥ 4 log.						

Table 2. Results of the activity of the test sample, with Poliovirus type 1 (ATCC VR-192) (Assay of titration with 12 wells), under test conditions requested by the client.

Assay	Concentration	Time of contact (sec/min)	Dilutions (log10) ^{a,b}									
			1	2	3	4	5	6	7	8	9	10
Test sample	80%	60 sec	4444	0321	2000	0000	0000	0000	0000	0000	NR	NR
			4444	0100	0023	0000	0000	0000	0000	0000	NR	NR
			4444	3004	0000	0000	0000	0000	0000	0000	NR	NR
	50%	60 sec	4444	4444	4444	0302	1233	0000	0000	0000	NR	NR
			4444	4444	4444	4443	0020	1000	0000	0000	NR	NR
			4444	4444	4444	3344	0102	0022	0000	0000	NR	NR
Cytotoxicity	80%	60 sec	4444	4444	4444	4444	4444	4344	0304	0000	NR	NR
			4444	4444	4444	4444	4444	2044	4432	0000	NR	NR
			4444	4444	4444	4444	4444	4302	0002	0200	NR	NR
Virus control	NA	0	0000	0000	0000	0000	0000	0000	0000	NR	NR	NR
			0000	0000	0000	0000	0000	0000	0000	NR	NR	NR
			0000	0000	0000	0000	0000	0000	0000	NR	NR	NR
		60 sec	4444	4444	4444	4444	4444	3024	0040	0200	NR	NR
			4444	4444	4444	4444	4444	4433	0203	0000	NR	NR
			4444	4444	4444	4444	4444	4423	3201	0000	NR	NR
Formaldehyde	0.7% (w:v)	30 min	4444	4444	4444	4444	4444	4332	0200	0000	NR	NR
			4444	4444	4444	4444	4444	2010	2342	0000	NR	NR
			4444	4444	4444	4444	4444	1324	0023	0010	NR	NR
		60 min	4444	4444	4444	3244	0130	0000	0000	NR	NR	NR
			4444	4444	4444	3200	0202	0000	0000	NR	NR	NR
			4444	4444	4444	1344	0003	0000	0000	NR	NR	NR
Control of formaldehyde cytotoxicity	0.7% (w:v)	30 min	4444	4444	4444	0000	0000	0000	0000	NR	NR	NR
			4444	4444	4444	0012	0000	0000	0000	NR	NR	NR
			4444	4444	3223	0001	2000	0000	0000	NR	NR	NR
		60 min	0000	0000	0000	0000	0000	0000	0000	NR	NR	NR
			0000	0000	0000	0000	0000	0000	0000	NR	NR	NR
			0000	0000	0000	0000	0000	0000	0000	NR	NR	NR
Virus control Formaldehyde	0.7% (w:v)	0	4444	4444	4444	4444	4444	4444	0240	0000	0000	0000
			4444	4444	4444	4444	4444	4444	3000	0000	0000	0000
			4444	4444	4444	4444	4444	4444	2003	0000	0000	0000
		60 min	4444	4444	4444	4444	4444	4023	0002	0000	0000	0000
			4444	4444	4444	4444	4444	4432	0210	0000	0000	0000
			4444	4444	4444	4444	4444	0134	0003	0000	0000	0000
Sensitivity control of cells to virus	NA	Cells not treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCC0	0000	0000	NR
			CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCC0	0000	0000	NR
			CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCC0	0000	0000	NR
		Cells treated	CCCC	CCCC	CCCC	CCCC	CCCC	0C0C	CCC0	0000	0000	NR
			CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0C0C	0000	0000	NR
			CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0C0C	0000	0000	NR
Effectiveness control of the disinfectant suppression activity	NA	Without sample	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	000C	0C00	0000	NR
			CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0CCC	CC00	0000	NR
			CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CC0C	0C0C	0000	NR
		With sample	CCCC	CCCC	CCCC	CCCC	CCCC	0C0C	0000	0000	0000	NR
			CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	C000	0000	0000	NR
			CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	C00C	0000	0000	NR

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.
C = cytopathic effect with presence of virus (in this case and according to Standard does not take into account the degree of cytopathic effect only, the presence or absence of the same).
0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; sec: seconds; min: minutes.

Table 3. Results of activity of the test sample with Adenovirus type 5 (ATCC VR-5), under test conditions requested by the client.

Assay	Concentration	log ₁₀ TCID ₅₀ after...				Reduction with the confidence interval of 95 %
		0 min	60 sec	30 min	60 min	
Test sample	80%	-	1.32	-	-	5.25 ± 0.57
	50%	-	2.41	-	-	4.16 ± 0.55
	0.1%	-	6.57	-	-	0.00 ± 0.61
Virus control	NA	6.74	6.57	-	-	NA
NA: not applicable; Times indicated by Standard for surface disinfection: maximum 5 or 60 min Times indicated by Standard for instrument disinfection: maximum 60 min Times indicated by Standard for textile disinfection: maximum 60 min Times indicated by Standard for hygienic hand treatment by friction and hygienic hand washing: between 30 and 120 seconds. Viricidal activity exists when the virus titer shows a reduction ≥ 4 log.						

Table 4. Results of the activity of the test sample, with Adenovirus type 5 (ATCC VR-5) (Assay of titration with 12 wells), under test conditions requested by the client.

Assay	Concentration	Time of contact (sec/min)	Dilutions (log10) ^{a,b}									
			1	2	3	4	5	6	7	8	9	10
Test sample	80%	60 sec	3210 0300 4322	0000 0002 0020	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	50%	60 sec	4444 4444 4444	0034 4322 0322	1000 0000 2000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	0.1%	60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3443 4420 0020	0000 2000 2303	0000 0000 1000	NR	NR
Cytotoxicity	80%	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control	NA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3442 0234 4404	020 3002 030	2000 0000 0000	NR	NR
		60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0321 3404 0043	0030 0200 1200	0000 0002 0000	NR	NR
Formaldehyde	0.7% (w:v)	30 min	4444 4444 4444	4444 4444 4444	0320 1000 2300	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
		60 min	4444 4444 4444	3210 1002 0033	0002 0012 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Control of formaldehyde cytotoxicity	0.7% (w:v)	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control Formaldehyde	0.7% (w:v)	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3440 0233 4043	0000 3010 203	0020 0000 0000	0000 0000 0000	NR
		60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3210 304 0444	0000 2022 0003	0000 0000 0000	0000 0000 0000	NR
Sensitivity control of cells to virus	NA	Cells not treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0C0C 0CCC 0CCC	00C0 00CC C00C	0000 0000 0000	NR
		Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0C00 C0CC C000	0000 0000 0000	0000 0000 0000	NR
Effectiveness control of the disinfectant suppression activity	NA	Without sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	00CC 00C0 0000	0000 0000 0000	NR	NR
		With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC C0CC CCCC	0000 00C0 000C	0000 0000 0000	NR	NR

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.

C = cytopathic effect with presence of virus (in this case and according to Standard does not take into account the degree of cytopathic effect only, the presence or absence of the same).

0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; sec: seconds; min: minutes.

Table 5. Results of activity of the test sample, with Murine Norovirus, strain S99 Berlin, under test conditions requested by the client.

Assay	Concentration	log ₁₀ TCID ₅₀ after...				Reduction with the confidence interval of 95 %
		0 min	60 sec	30 min	60 min	
Test sample	80%	-	0.50	-	-	$\geq 7.58 \pm 0.34$
	50%	-	2.82	-	-	5.26 ± 0.53
	0.1%	-	7.99	-	-	0.09 ± 0.53
Virus control	NA	8.16	8.08	-	-	NA
NA: not applicable; Times indicated by Standard for surface disinfection: maximum 5 or 60 min Times indicated by Standard for instrument disinfection: maximum 60 min Times indicated by Standard for textile disinfection: maximum 60 min Times indicated by Standard for hygienic hand treatment by friction and hygienic hand washing: between 30 and 120 seconds. Viricidal activity exists when the virus titer shows a reduction ≥ 4 log.						

Table 6. Results of the activity of the test sample, with Murine Norovirus strain S99 Berlin (Assay of titration with 12 wells), under test conditions requested by the client.

Assay	Concentration	Time of contact (sec/min)	Dilutions (log10) ^{a,b}									
			1	2	3	4	5	6	7	8	9	10
Test sample	80%	60 sec	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	50%	60 sec	4444 4444 4444	0434 4442 0234	0003 0021 2003	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	0.1%	60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0304 4433 4442	4220 3003 2001	0000 0000 0200	NR
Cytotoxicity	80%	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control	NA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0302 0134 0040	0000 0200 0002	0000 0000 0000
		60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0302 4400 0303	0000 0002 000	0000 0000 0000
Formaldehyde	0.7% (w:v)	30 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	3443 2134 4404	2320 0203 0003	0000 0000 1030	0000 0000 0000	NR	NR	NR
		60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	0020 3000 1200	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Control of formaldehyde cytotoxicity	0.7% (w:v)	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control Formaldehyde	0.7% (w:v)	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3420 2344 0331	0000 0100 2302	0000 0000 0000	0000 0000 0000
		60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0304 0443 0444	1200 0000 3002	0000 0000 0000	0000 0000 0000
Sensitivity control of cells to virus	NA	Cells not treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	C0CC CCCC CCCC	00C0 00CC C00C	0000 0C00 0000
		Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	00C0 C00C CCC0	0000 0C00 00C0	0000 0000 0000
Effectiveness control of the disinfectant suppression activity	NA	Without sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CC0C CCCC	0000 CCC0 C00C	0000 0000 0000	0000 0000 0000
		With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	C0CC 0CCC CCC0	00C0 0000 C00C	0000 0000 0000	0000 0000 0000

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.

C = cytopathic effect with presence of virus (in this case and according to Standard does not take into account the degree of cytopathic effect only, the presence or absence of the same).

0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; sec: seconds; min: minutes.

Figure 1. Results of the activity of the test sample under test conditions requested by the client with Poliovirus type 1 (ATCC VR-192).

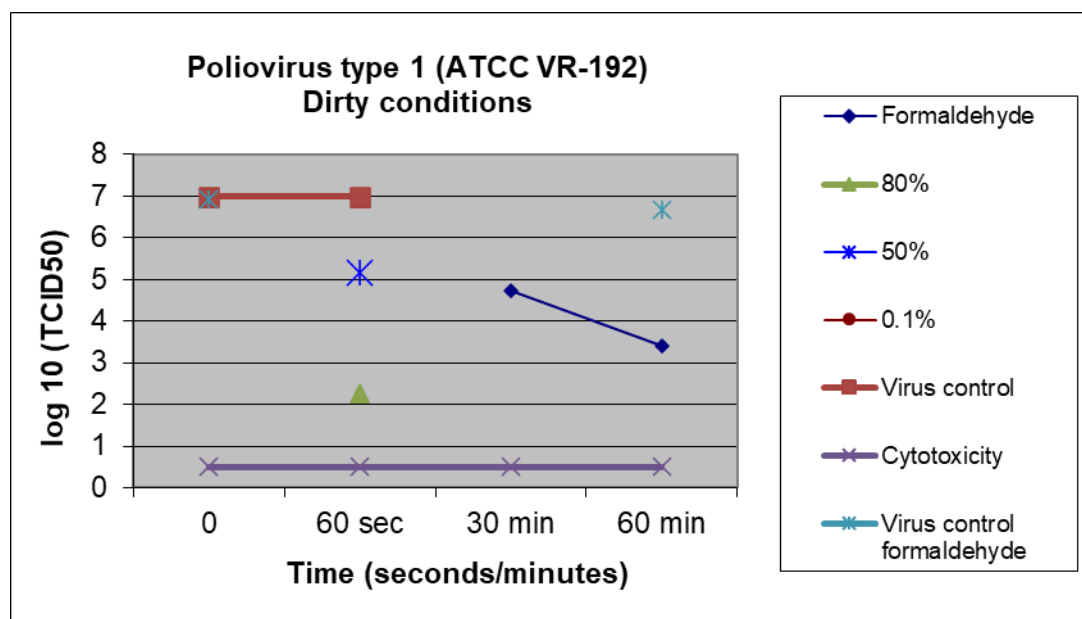


Figure 2. Results of the activity of the test sample under test conditions requested by the client with Adenovirus type 5 (ATCC VR-5).

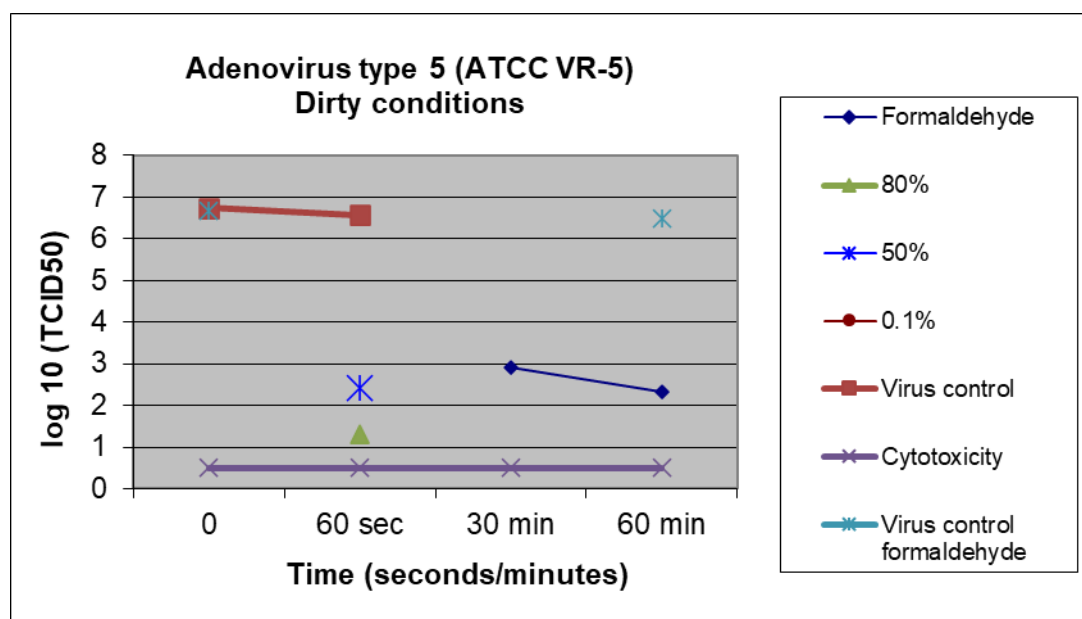


Figure 3. Results of the activity of the test sample under test conditions requested by the client with Murine Norovirus strain S99 Berlin.

