MINISTERUL SĂNĂTĂŢII AL REPUBLICII MOLDOVA

AGENŢIA NAŢIONALĂ PENTRU SĂNĂTATE PUBLICĂ

MD 2028, mun. Chişinău, str. Gh. Asachi 67A, Tel. +373 22 574 501, https://ansp.md e-mail: office@ansp.gov.md IDNO:1018601000021

CERTIFICAT
DE ÎNREGISTRARE DE STAT

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Nr.	B-0276/2025
din	03.09.2025

I. Denumirea comercială a produsului în Republica Moldova

Şervețele umede dezinfectante "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. Categoria 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 si 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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Vasile Gustiuc

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Date: 2025.10.21 09:34:19 EEST
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Anexa 1
la certificatul nr. B-0276/2025 din 03.09.2025 pentru înregistrare de stat a produsului biocid

I. Denumirea comercială a produsului în Republica Moldova

Șervețele umede dezinfectante "Amigam"

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

Denumirea chimică (IUPAC, ISO sau alte)	*Nr. CE*	*Nr. CAS*	*Cantitatea în produs*
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

servețele

VIII. Modul de ambalare (tipul, capacitatea)

recipient din polimer dens, ambalaje moi sau individuale/capacitate 1-200

IX. Domeniul și aria de utilizare

1. Domeniul de utilizare	Igiena umană. Dezinfectante şi algicide care nu sunt destinate aplicării directe a oameni sau animale.
2. Aria de aplicare	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

Activitatea	*Metoda de testare/protocolul de testare*	*Specia/tulpina*	*Concentrații*	*Timp de acțiune*
Bactericidă în condiții de murdarie	EN 13727:2012+A2:2015	Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae, Escherichia coli K12	50%, 80%	60 sec.
Fungicidă în condiții de murdarie	EN 13624:2021	Candida albicans, Aspergillus brasiliensis	80%	60 sec.
Mycobactericidă în condiții de murdarie	EN 14348:2005	Mycobacterium avium, Mycobacterium terrae	80%	60 sec.
Virucidă in condiții de murdarie	EN 14476:2013+A1:2019	Poliovirus type 1, Adenovirus type 5, Murine norovirus	80%	60 sec.

XI. Indicații de utilizare

Metoda de aplicare	*Concentrația soluției de lucru*	*Timpul de acțiune*
dezinfectia mainilor prin frecare	gata pentru utilizare	60 sec.
dezinfectia prin stergere suprafețelor	gata pentru utilizare	60 sec

XII.	**Etichetarea produsului biocid**
Simboluri și indicarea pericolelor	Pericol.DANCER
Fraze de risc (R) și/sau Pictograme de pericol (H)	R7 Poate provoca un incendiu.
Fraze de prudență (S) și/sau Fraze de precauție (P)	S2 A nu se lasa la îndemana copiilor.

XIII. Categoria de utilizatori

Profesionali, Populatie, Industriali,

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

Utilizare conform instrucțiunii.

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Date: 2025.10.21 10:39:16 EEST
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Location: Moldova
MOLDOVA EUROPEANĂ

Instituto Valenciano de Microbiología

Masía El Romeral
Ctra. Bétera – San Antonio de Benagéber, Km 0,3
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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 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 alcool 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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ENAC
ENSAYO
ISO 17025
Nº648 / LE1286

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 ……. 20ºC ± 1ºC.
- 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 …… +30ºC ± 1ºC.
- 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 20ºC ±1ºC, 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 (***Nv*$_0$**)			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 ≤ ***X*** of ***Nv*$_0$** ≤ 160? Yes			***X*** of ***A*** is ≥0.5x ***X*** if ***Nv*$_0$**? Yes			***X*** of ***B*** is ≥ 0,5 x ***X*** of ***Nv*$_0$**,** or ***Nv*$_B$**/1000*?* Yes			***X*** of ***C*** is ≥0.5x ***X*** of ***Nv*$_0$**? Yes		
Suspension of validation ***(N*$_{vB}$*)***			***Vc*$_1$*:*** 54 ***Vc*$_2$*:*** 56			***X*** = 55 30 ≤ x of ***N*$_{vB}$**/1000 ≤ 160? Yes					

Table 2.-Suspension of the assay.

	N	***Vc*$_1$**	***V*$_{C2}$**	
Suspension of assay (***N*** and ***N*$_0$**)	10^{-5}	150	156	***Xwm*** = 1.56 x 10^7 lg***N*** = 7.19 ***N*$_0$** = ***N***/10 lg ***N*$_0$** = 6.19 6.17 ≤ lg***N*$_0$** ≤ 6.70? Yes
	10^{-6}	17	20	

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

Concentrations of the sample (%)	**Dilution steps**	***Vc*$_1$**	***Vc*$_2$**	Lg ***Na*** = lg (***X*** x 10 o ***Xwm*** x 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 **(Nv_0)**			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
$30 \leq X$ of $Nv_0 \leq 160$? Yes			X of A is ≥0.5x X if Nv_0? Yes			X of B is ≥ 0,5 x X of Nv_0, or $Nv_B/1000$? Yes			X of C is ≥0.5x X of Nv_0? Yes		
Suspension of validation (N_{vB})			Vc_1: 60 Vc_2: 65			X = 62.5 $30 \leq$ x of $N_{vB}/1000 \leq 160$? Yes					

Table 5.-Suspension of the assay.

	N	Vc_1	V_{C2}	
Suspension of assay (N and N_0)	10^{-5}	166	167	Xwm = 1.71 x 10^7 lg$N$ = 7.23 $N_0 = N/10$ lg N_0 = 6.23 $6.17 \leq \lg N_0 \leq 6.70$? Yes
	10^{-6}	20	23	

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

Sample concentration (%)	**Dilution step**	Vc_1	Vc_2	lg Na = lg (X x 10 or Xwm x 10)	lg R (lgN_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 alcool 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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ENSAYO
ISO 17025
Nº648 / LE1286

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 ……..... 20ºC ± 1ºC.
- 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 ……. +36ºC ± 1ºC.
- 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 20ºC ± 1ºC, 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 (*Nv*$_0$)			**Control of experimental conditions (*A*)**			**Control of the neutralization (*B*)**			**Validation of the method (*C*) Sample concentration: 80%**		
***Vc*$_1$**	44	***X*=**	***Vc*$_1$**	39	***X*=**	***Vc*$_1$**	43	***X*=**	***Vc*$_1$**	40	***X*=**
***Vc*$_2$**	45	44.5	***Vc*$_2$**	39	39	***Vc*$_2$**	40	41.5	***Vc*$_2$**	36	38
30 ≤ ***X*** of ***Nv*$_0$** ≤ 160? Yes			***X*** of ***A*** is ≥ 0.5 ***X*** of ***Nv*$_0$**? Yes			***X*** of ***B*** is ≥ 0.5 ***X*** of ***Nv*$_0$**? Yes			***X*** of ***C*** is ≥ 0.5 ***X*** of ***Nv*$_0$**? Yes		
Suspension of validation (*Nv*$_B$)			***Vc*$_1$**: 50 ***Vc*$_2$**: 56			***X*** = 53 30 ≤ ***X*** of ***Nv*$_B$**/1000 ≤ 160? Yes					

Table 2.-Suspension of the assay

	N	***Vc*$_1$**	***Vc*$_2$**	
Suspension of assay (***N*** and ***N*$_0$**)	10^{-6}	208	210	***Xwm*** = 2.18 x 10^8, lg ***N*** = 8.34 ***N*$_0$** = ***N***/10; lg ***N*$_0$** = 7.34 7.17 ≤ lg ***N*$_0$** ≤ 7.70? Yes
	10^{-7}	30	32	

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

Concentrations of the sample (%)	Dilutions steps	***Vc*$_1$**	***Vc*$_2$**	Lg ***Na*** = lg (***X*** x 10 o ***Xwm*** x 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:
Vc = number per mL (one or two plates); ***Xwm*** = weighted mean of ***X***.
X = mean of ***Vc*$_1$** and ***Vc*$_2$** (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 (*Nv*$_0$)			**Control of experimental conditions (*A*)**			**Control of the neutralization (*B*)**			**Validation of the method (*C*) Sample concentration: 80%**		
***Vc*$_1$**	48	***X*=**	***Vc*$_1$**	35	***X*=**	***Vc*$_1$**	53	***X*=**	***Vc*$_1$**	43	***X*=**
***Vc*$_2$**	46	47	***Vc*$_2$**	36	35.5	***Vc*$_2$**	57	55	***Vc*$_2$**	39	41
30 ≤ ***X*** of ***Nv*$_0$** ≤ 160? Yes			***X*** of ***A*** is ≥ 0.5 ***X*** of ***Nv*$_0$**? Yes			***X*** of ***B*** is ≥ 0.5 ***X*** of ***Nv*$_0$**? Yes			***X*** of ***C*** is ≥ 0.5 ***X*** of ***Nv*$_0$**? Yes		
Suspension of validation (*Nv*$_B$)			***Vc*$_1$**: 75 ***Vc*$_2$**: 76			***X*** = 75.5 30 ≤ ***X*** of ***Nv*$_B$**/1000 ≤ 160? Yes					

Table 5.-Suspension of the assay

	N	***Vc*$_1$**	***Vc*$_2$**	
Suspension of assay (***N*** and ***N*$_0$**)	10^{-6}	248	242	***Xwm*** = 2.48 x 10^8, lg ***N*** = 8.39 ***N*$_0$** = ***N***/10; lg ***N*$_0$** = 7.39 7.17 ≤ lg ***N*$_0$** ≤ 7.70? Yes
	10^{-7}	29	27	

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

Concentrations of the sample (%)	Dilutions steps	***Vc*$_1$**	***Vc*$_2$**	Lg ***Na*** = lg (***X*** x 10 o ***Xwm*** x 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:
Vc = number per mL (one or two plates); ***Xwm*** = weighted mean of ***X***.
X = mean of ***Vc*$_1$** and ***Vc*$_2$** (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 (*Nv*$_0$)			**Control of experimental conditions (*A*)**			**Control of the neutralization (*B*)**			**Validation of the method (*C*) Sample concentration: 80%**		
***Vc*$_1$**	55	***X***=	***Vc*$_1$**	49	***X***=	***Vc*$_1$**	57	***X***= 58	***Vc*$_1$**	51	***X***=
***Vc*$_2$**	50	52.5	***Vc*$_2$**	41	45	***Vc*$_2$**	59		***Vc*$_2$**	47	49
30 ≤ ***X*** of ***Nv*$_0$** ≤ 160? Yes			***X*** of ***A*** is ≥ 0.5 ***X*** of ***Nv*$_0$**? Yes			***X*** of ***B*** is ≥ 0.5 ***X*** of ***Nv*$_0$**? Yes			***X*** of ***C*** is ≥ 0.5 ***X*** of ***Nv*$_0$**? Yes		
Suspension of validation (*Nv*$_B$)			***Vc*$_1$**: 61 ***Vc*$_2$**: 63			***X*** = 62 30 ≤ ***X*** of ***Nv*$_B$**/1000 ≤ 160? Yes					

Table 8.-Suspension of the assay

	N	***Vc*$_1$**	***Vc*$_2$**	
Suspension of assay (***N*** and ***N*$_0$**)	10^{-6}	224	219	***Xwm*** = 2.23 x 10^8, lg ***N*** = 8.35 ***N*$_0$** = ***N***/10; lg ***N*$_0$** = 7.35 7.17 ≤ lg ***N*$_0$** ≤ 7.70? Yes
	10^{-7}	27	21	

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

Concentrations of the sample (%)	Dilutions steps	***Vc*$_1$**	***Vc*$_2$**	Lg ***Na*** = lg (***X*** x 10 o ***Xwm*** x 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:
Vc = number per mL (one or two plates); ***Xwm*** = weighted mean of ***X***.
X = mean of ***Vc*$_1$** and ***Vc*$_2$** (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 (Nv_0)			**Control of experimental conditions (*A*)**			**Control of the neutralization (*B*)**			**Validation of the method (*C*) Sample concentration: 80%**		
Vc_1	42	X=	Vc_1	41	X=	Vc_1	46	X=	Vc_1	45	X=
Vc_2	48	45	Vc_2	46	43.5	Vc_2	48	47	Vc_2	38	41.5
$30 \leq X$ of $Nv_0 \leq 160$? Yes			X of A is ≥ 0.5 X of Nv_0? Yes			X of B is ≥ 0.5 X of Nv_0? Yes			X of C is ≥ 0.5 X of Nv_0? Yes		
Suspension of validation (Nv_B)			Vc_1: 50 Vc_2: 53			X = 51.5 $30 \leq X$ of $Nv_B/1000 \leq 160$? Yes					

Table 11.-Suspension of the assay

	N	Vc_1	Vc_2	
Suspension of assay (N and N_0)	10^{-6}	167	181	Xwm = 1.79 x 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^{-7}	22	24	

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

Concentrations of the sample (%)	Dilutions steps	Vc_1	Vc_2	Lg Na = lg (X x 10 o Xwm x 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:
Vc = number per mL (one or two plates); Xwm = weighted mean of X.
X = mean of Vc_1 and Vc_2 (duplicate of 1 + 2);
Logarithmic reduction R: ($\lg R = \lg N_0 - \lg Na$).

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 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 alcool 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 09:34:35 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

ENAC
ENSAYO
ISO 17025
Nº648 / LE1286

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 ....…….... $TCID_{50}$ (Tissue Culture Infective Dose 50%).
- Incubation temperature ……. 37ºC ±1ºC.
- Product concentrations for the assay .... 80%, 50% and 0.1%.
- Contact time ..……..... 60 seconds.
- Contact temperature ..……... 20ºC ±1ºC.
- 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 $TCID_{50}$**
• 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 $TCID_{50}$**
• 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 $TCID_{50}$**
• 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 $\log_{10}$. 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 $\log_{10}$ reduction in the virus titer.

Interference control – control of cell susceptibility

Poliovirus type 1 (ATCC VR-192)	**log $TCID_{50}$**
• 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 $TCID_{50}$**
• 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 $TCID_{50}$**
• 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 $TCID_{50}$**
• 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 $TCID_{50}$**
• 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 $TCID_{50}$**
• 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 $TCID_{50}$**	
• 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 $TCID_{50}$**	
• 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 $TCID_{50}$**	
• 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.
$TCID_{50}$: 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 20ºC 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»"**, batch14062028, **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	Concen-tration	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 4444 4444	0321 0100 3004	2000 0023 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	50%	60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	0302 4443 3344	1233 0020 0102	0000 1000 0022	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	4344 2044 4302	0304 4432 0002	0000 0000 0200	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	3024 4433 4423	0040 0203 3201	0200 0000 0000	NR	NR
		60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4332 2010 1324	0200 2342 0023	0000 0000 0010	NR	NR
Formaldehyde	0.7% (w:v)	30 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	3244 3200 1344	0130 0202 0003	0000 0000 0000	0000 0000 0000	NR	NR	NR
		60 min	4444 4444 4444	4444 4444 4444	0302 4400 3223	0000 0012 0001	0000 0000 2000	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	0240 3000 2003	0000 0000 0000	0000 0000 0000	0000 0000 0000
		60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4023 4432 0134	0002 0210 0003	0000 0000 0000	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	CCC0 C0CC CC00	0000 0CC0 0000	0000 0000 0000	NR
		Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0C0C CCCC CCCC	CCC0 00C0 0CC0	0000 0000 000C	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 0CCC CC0C	000C CC00 0C0C	0C00 0000 0000	0000 0000 0000	NR
		With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0C0C CCCC 0CCC	0000 C000 C00C	0000 0000 0000	0000 0000 0000	NR

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or gradeof 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	Concen-tration	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 000C 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 CCC0	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 gradeof 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	-	-	≥ 7.58 ± 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	Concen-tration	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 CCC0 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 gradeof 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).

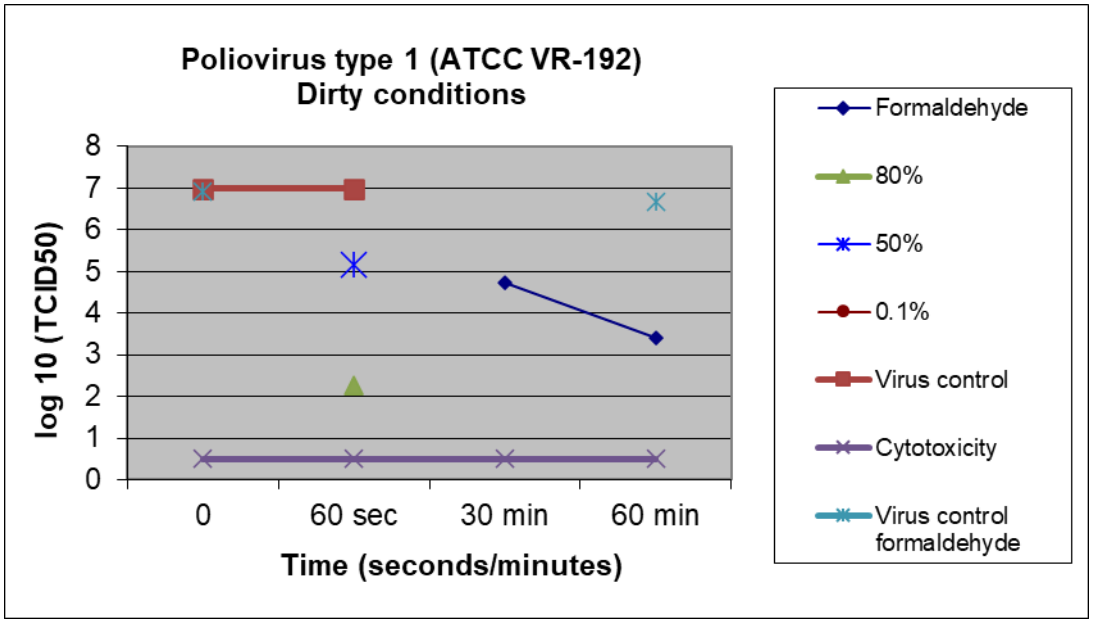

Figure 2. Results of the activity of the test sample under test conditions requested by the client with Adenovirus type 5 (ATCC VR-5).

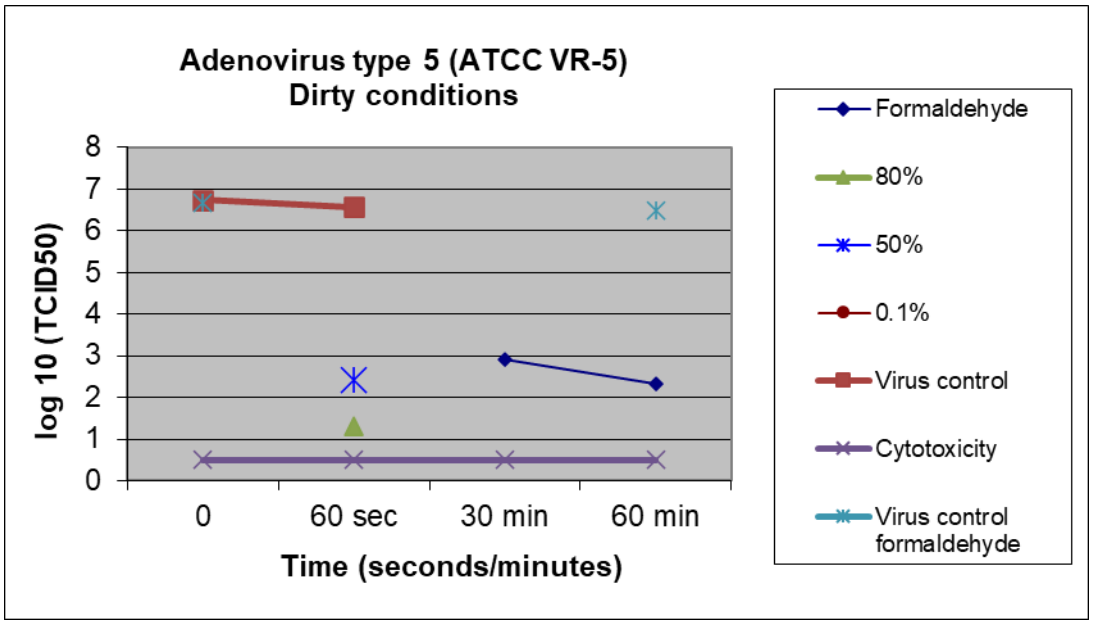

Figure 3. Results of the activity of the test sample under test conditions requested by the client with Murine Norovirus strain S99 Berlin.