ECOLAB®

Research & Development Healthcare
Europe, Middle East, Africa
Microbiological Support

Statement on the fungicidal effect of Incidin active according to EN 13624

It is hereby confirmed that FC FC 913019 as tested according to Anios studies n° 36772, report N° A 18 43 13624 and n° 36828, report N° A 18 60 13624 is identical to Incidin active.

In conclusion of report N° A 18 43 13624 and N° A 18 60 13624 Incidin active is therefore effective against moulds according to EN 13624 under clean conditions at a concentration of 1% with a contact time of 60 min and at a concentration of 2% at a contact time of 15 min .

Monheim am Rhein, April 9th 2018

Sebastian Niebur
Principal Technical Service Specialist II
RD&E Healthcare EMEA

Dr. Bernhard Meyer
Senior Staff Scientist
RD&E Healthcare EMEA

Digitally signed by Bunic Gheorghe
Date: 2023.11.07 15:33:20 EET
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Location: Moldova

Test report no L16/0084.1

Quantitative test method for the evaluation of bactericidal and yeasticidal activity of **Incidin Active** on non-porous surfaces with mechanical action employing wipes in the medical area according to DIN EN 16615:2015 (Phase 2, step 2)*

In accordance with your order, we tested the preparation **Incidin Active** for its activity in the quantitative surface test according to DIN EN 16615:2015* under dirty conditions.

1 General Information and Material

1.1 Client

Client:	ECOLAB DEUTSCHLAND GMBH, Herrn Dr. Bernhard Meyer Ecolab-Allee 1, DE - 40789 Monheim am Rhein, Germany
Date of order:	26/01/2016

1.2 Identification of Test Laboratory

Location:	Dr. Brill + Partner GmbH · Institute for Hygiene and Microbiology, Stiegstück 34, DE-22339 Hamburg, Germany
Study manager:	Dipl.-Biol. Henrik Gabriel
Scientific assistant:	Dipl.-Ing. Dr. rer. nat. Andreas Kampe
Laboratory technicians:	Martina Müller

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1.4 Identification of Sample

Name of product:	**Incidin Active**
Batch no.:	1245FM0707

Manufacturer:	ECOLAB DEUTSCHLAND GMBH, Monheim am Rhein, Germany
Date of delivery:	01/02/2016
Storage conditions:	room temperature and darkness
Appearance of product:	powder
Odour:	characteristic
Product type:	Surface Disinfectant
Recommended diluent:	Tap water
Diluent used:	water of standardised hardness (WSH, pH 7.0)
Active agents (Manufacturer's data):	0.1 % peracetic acid

1.5 Test Conditions

Test period:	15/03/ - 03/05/2016	
Product test concentrations:	Standard organisms:	0.1 + 1.0 %
	Additional organisms:	0.2 + 2.0 %
Exposure time:	1 + 5 minutes	
Germ carrier:	PVC tile, 20 cm x 50 cm	
Test temperature:	20°C ± 1°C	
Incubation temperature:	36°C ± 1°C	
Organic load:	dirty conditions (3.0 g/L bovine albumin + 3.0 g/L sheep erythrocytes)	
Standard wipe:	Tork Premium Special Wipes (SCA Tork), 17.5 x 28 cm, No. 90491	
Impregnation volume:	16 ml	
Impregnation time:	min. 30 minutes	
Neutraliser:	30 g/L polysorbate 80, 30 g/L saponine, 3 g/L lecithin,1 g/L histidine, 5 g/L sodium thiosulphate (TLSH-Nt)	
Test organisms:	*Staphylococcus aureus*	ATCC 6538
	Enterococcus hirae	ATCC 10541
	Pseudomonas aeruginosa	ATCC 15442
	Candida albicans	ATCC 10231
	Mycobacterium terrae	ATCC 15755
	Mycobacterium avium	ATCC 15769

2 Methods

The tests were carried out according to EN 16615:2015 "Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) -Test method and requirements (phase 2, step 2)".

In addition to the standard test organisms *Mycobacterium terrae* and *Mycobacterium avium* were tested to show mycobactericidal efficacy.

3 Results

The test results based on DIN EN 16615: 2015 are summarised in tables 1 and were evaluated according to "Requirements and methods for VAH certification of chemical disinfection procedures, method 14" (as of 2 April 2015).

The test organisms were sufficiently (Standard Bacteria RF ≥ 5; Candida, Mycobacteria RF ≥ 4) inactivated with the following concentration-time relationship:

Bactericidal:	dirty conditions	1.0 %	5 minutes
Yasticidal:	dirty conditions	1.0 %	5 minutes
Mycobactericidal:	dirty conditions	2.0 %	5 minutes

Hamburg, 09/05/2016

Dipl.-Biol. Henrik Gabriel
Study Manager

Dipl.-Ing. Dr. rer. nat. Andreas Kampe
Quality control

Table 1.1: Summary of two test runs

Test organism	Contact time [min]	product concentration [%]	Field 1 log Reduction 1	2	3	Field 2-4 CFU/25cm² 1	2	3	Wipe control Field 2-4 CFU/25cm² 1	2+3
S. aureus	1	0.1	4.39			15			>16500	
	1	1	≥5.80			68.33			>16500	
	5	0.1	≥5.83			21.67			>16500	
	5	1	≥5.83			1.67			>16500	
E. hirae	1	0.1	≤3.07			25			1983	
	1	1	≥5.75			0			1983	
	5	0.1	4.92			5			1983	
	5	1	≥5.74	≥5.54	≥5.54	0	0	0	1983	12
	mean 5 min	1	**≥5.61**			**0**			**997.5**	
P. aeruginosa	1	0.1	4.93			5			133	
	1	1	≥5.74			0			133	
	5	0.1	≥5.54			3.33			133	
	5	1	≥5.54			0			133	
M. terrae	1	0.2	≤2.75			>1650			>16500	
	1	2	5.14			35			>16500	
	5	0.2	≤2.88			>1650			>16500	
	5	2	≥5.56	≥6.14	5.51	0	16.67	5	>16500	>16500
	mean 5 min	2	**≥5.74**			**7.22**			**>16500**	
M. avium	1	0.2	≤2.54			253			550	
	1	2	≥5.22			0			550	
	5	0.2	≥5.06			155			535	
	5	2	≥5.06	5.15	5.57	3.33	0	1.67	535	>7017
	mean 5 min	2	**≥5.26**			**1.67**			**>3776**	
C. albicans	1	0.1	≥4.60			13.33			142	
	1	1	≥4.49			0			142	
	5	0.1	≥4.22			6.67			142	
	5	1	≥4.22	≥4.07	≥4.07	0	0	0	142	20
	mean 5 min	1	**≥4.12**			**0**			**81**	

Table 1.2: Validation, Controls and Evaluation

Product name: **Incidin Active**
Test organism: *Staphylococcus aureus*
Contact time: **1 minute**

Batch: 1245FM0707
Organic load: dirty conditions
Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			1 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	77		75	V_{c1}	72		69,5	V_{c1}	78		75,5
V_{c2}	73			V_{c2}	67			V_{c2}	73		
30 ≤ $\bar{x}$ of N_{v0} ≤ 160			**Yes**	$\bar{x}$ of B is ≥ 0,5 x $\bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is ≥ 0,5 x $\bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	7,88 ≤ N_{V0} ≤ 8,40 ?
	1,00E-07	>330		>330		>660	>660	4,75E+09	8,33	**Yes**
	1,00E-08	53		42		53	42	9,68		
Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ * 5	lg T_0	6,88 ≤ T_0 ≤ 8,40 ?
	1,00E-04	>330		>330		>660	>660	4,05E+07	7,61	**Yes**
	1,00E-05	74		88		74	88			
Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ * 5	N_0=N/10; lg N_0	6,88 ≤ T_t ≤ 8,40 ?
	1,00E-04	>330		>330		>660	>660	4,40E+07	7,64	**Yes**
	1,00E-05	86		90		86	90			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm}$ * 5)	lg N_a	lg R (lg T_t =7,64)
0,1	1,00E+00	>330		>330		>330	>330	1,80E+03	3,26	4,39
	1,00E-01	34		38		34	38			
1,0	1,00E+00	0		0		<14	<14	<7,00E+01	< 1,85	≥ 5,80
	1,00E-01	0		0		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
0,1	1,00E+00	6	0	3	15,00	**Yes**
1,0	1,00E+00	0	0	41	68,33	No

***N_W* test fields 2-4 (CFU/25 cm²)**

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	>16500	**Yes**
	1,00E-01	>330	>330	>330		

Table 1.3: Validation, Controls and Evaluation

Product name: **Incidin Active**
Test organism: *Staphylococcus aureus*
Contact time: **5 minutes**

Batch: 1245FM0707
Organic load: dirty conditions
Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			1 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	77		75	V_{c1}	72		69,5	V_{c1}	78		75,5
V_{c2}	73			V_{c2}	67			V_{c2}	73		
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count		V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	$7,88 \leq N_{V0} \leq 8,40$?
	1,00E-07	>330	>330	>660	>660	4,75E+09	8,33	**Yes**
	1,00E-08	53	42	53	42	9,68		
Control test for drying (D_{C0})	T_0	Microbial count		V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	lg T_0	$6,88 \leq T_0 \leq 8,40$?
	1,00E-04	>330	>330	>660	>660	4,05E+07	7,61	**Yes**
	1,00E-05	74	88	74	88			
Control test for drying after t (D_{Ct})	T_t	Microbial count		V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	N_0=N/10; lg N_0	$6,88 \leq T_t \leq 8,40$?
	1,00E-04	>330	>330	>660	>660	4,75E+07	7,68	**Yes**
	1,00E-05	92	98	92	98			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count		V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm} * 5$)	lg N_a	lg R (lg T_t =7,68)
0,1	1,00E+00	2	4	<14	<14	<7,00E+01	< 1,85	≥ 5,83
	1,00E-01	0	0	<14	<14			
1,0	1,00E+00	10	15	<14	15	<7,00E+01	< 1,85	≥ 5,83
	1,00E-01	0	0	<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm} * 5$) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
0,1	1,00E+00	2	2	9	21,67	**Yes**
1,0	1,00E+00	0	1	0	1,67	**Yes**

N_W test fields 2-4 (CFU/25 cm²)

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm} * 5$) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	>16500	**Yes**
	1,00E-01	>330	>330	>330		

Table 1.4: Validation, Controls and Evaluation

Product name: **Incidin Active**
Test organism: *Enterococcus hirae*
Contact time: **1 minute**

Batch: 1245FM0707
Organic load: dirty conditions
Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			1 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	97		94,5	V_{c1}	89		90	V_{c1}	94		94
V_{c2}	92			V_{c2}	91			V_{c2}	94		
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	$7,88 \leq N_{V0} \leq 8,40$?
	1,00E-07	>330		>330		>660	>660	4,45E+09	8,30	**Yes**
	1,00E-08	48		41		48	41	9,65		
Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	lg T_0	$6,88 \leq T_0 \leq 8,40$?
	1,00E-04	>330		>330		>660	>660	2,85E+07	7,45	**Yes**
	1,00E-05	60		54		60	54			
Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	N_0=N/10; lg N_0	$6,88 \leq T_t \leq 8,40$?
	1,00E-04	>330		>330		>660	>660	3,90E+07	7,59	**Yes**
	1,00E-05	74		82		74	82			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm}$ * 5)	lg N_a	lg R (lg T_t =7,59)
0,1	1,00E+00	>330		>330		>330	>330	>3,30E+04	> 4,22	≤ 3,07
	1,00E-01	>330		>330		>330	>330			
1,0	1,00E+00	10		14		<14	<14	<7,00E+01	< 1,85	≥ 5,75
	1,00E-01	0		0		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
0,1	1,00E+00	5	4	6	25,00	**Yes**
1,0	1,00E+00	0	0	0	0,00	**Yes**

N_W test fields 2-4 (CFU/25 cm²)

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	1983	**Yes**
	1,00E-01	21	51	47		

Table 1.5: Validation, Controls and Evaluation

Product name: **Incidin Active**
Test organism: *Enterococcus hirae*
Contact time: **5 minutes**

Batch: 1245FM0707
Organic load: dirty conditions
Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			1 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	97		94,5	V_{c1}	89		90	V_{c1}	94		94
V_{c2}	92			V_{c2}	91			V_{c2}	94		
30 ≤ $\bar{x}$ of N_{v0} ≤ 160			**Yes**	$\bar{x}$ of B is ≥ 0,5 x $\bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is ≥ 0,5 x $\bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	7,88 ≤ N_{V0} ≤ 8,40 ?
	1,00E-07	>330		>330		>660	>660	4,45E+09	8,30	**Yes**
	1,00E-08	48		41		48	41	9,65		
Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ * 5	lg T_0	6,88 ≤ T_0 ≤ 8,40 ?
	1,00E-04	>330		>330		>660	>660	2,85E+07	7,45	**Yes**
	1,00E-05	60		54		60	54			
Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ * 5	N_0=N/10; lg N_0	6,88 ≤ T_t ≤ 8,40 ?
	1,00E-04	>330		>330		>660	>660	3,85E+07	7,59	**Yes**
	1,00E-05	80		74		80	74			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm}$ * 5)	lg N_a	lg R (lg T_t =7,59)
0,1	1,00E+00	80		106		80	106	4,65E+02	2,67	4,92
	1,00E-01	6		7		<14	<14			
1,0	1,00E+00	0		0		<14	<14	<7,00E+01	< 1,85	≥ 5,74
	1,00E-01	0		0		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
0,1	1,00E+00	1	1	1	5,00	**Yes**
1,0	1,00E+00	0	0	0	0,00	**Yes**

N_W test fields 2-4 (CFU/25 cm²)

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	1983	**Yes**
	1,00E-01	21	51	47		

Table 1.6: Validation, Controls and Evaluation

Product name: **Incidin Active**
Test organism: *Enterococcus hirae*
Contact time: **5 minutes**

Batch: 1245FM0707
Organic load: dirty conditions
Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			1 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	64		62	V_{c1}	70		65	V_{c1}	45		54,5
V_{c2}	60			V_{c2}	60			V_{c2}	64		
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count			V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	7,88 ≤ N_{V0} ≤ 8,40 ?
	1,00E-07	>330	>330		>660	>660	2,65E+09	8,08	**Yes**
	1,00E-08	31	22		31	22	9,42		
Control test for drying (D_{C0})	T_0	Microbial count			V_{c1}	V_{c2}	$\bar{x}_{wm}$ * 5	lg T_0	6,88 ≤ T_0 ≤ 8,40 ?
	1,00E-04	>330	>330		>660	>660	2,70E+07	7,43	**Yes**
	1,00E-05	52	56		52	56			
Control test for drying after t (D_{Ct})	T_t	Microbial count			V_{c1}	V_{c2}	$\bar{x}_{wm}$ * 5	N_0=N/10; lg N_0	6,88 ≤ T_t ≤ 8,40 ?
	1,00E-04	>330	>330		>660	>660	2,45E+07	7,39	**Yes**
	1,00E-05	50	48		50	48			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count			V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm}$ * 5)	lg N_a	lg R (lg T_t =7,39)
1,0	1,00E+00	0	2		<14	<14	<7,00E+01	< 1,85	≥ 5,54
	1,00E-01	0	0		<14	<14			
1,0	1,00E+00	0	0		<14	<14	<7,00E+01	< 1,85	≥ 5,54
	1,00E-01	0	0		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
1,0	1,00E+00	0	0	0	0,00	**Yes**
1,0	1,00E+00	0	0	0	0,00	**Yes**

***N_W* test fields 2-4 (CFU/25 cm²)**

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	7	0	0	12	**Yes**
	1,00E-01	0	0	0		

Table 1.7: Validation, Controls and Evaluation

Product name: **Incidin Active**
Test organism: *Pseudomonas aeruginosa*
Contact time: **1 minute**

Batch: 1245FM0707
Organic load: dirty conditions
Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			1 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	78		75	V_{c1}	80		81	V_{c1}	82		83
V_{c2}	72			V_{c2}	82			V_{c2}	84		
30 ≤ $\bar{x}$ of N_{v0} ≤ 160			**Yes**	$\bar{x}$ of B is ≥ 0,5 x $\bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is ≥ 0,5 x $\bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	7,88 ≤ N_{V0} ≤ 8,40 ?
	1,00E-07	>330		>330		>660	>660	3,45E+09	8,19	**Yes**
	1,00E-08	39		30		39	30	9,54		

Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ * 5	lg T_0	6,88 ≤ T_0 ≤ 8,40 ?
	1,00E-04	>330		>330		>660	>660	2,90E+07	7,46	**Yes**
	1,00E-05	48		68		48	68			

Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ * 5	N_0=N/10; lg N_0	6,88 ≤ T_t ≤ 8,40 ?
	1,00E-04	>330		>330		>660	>660	2,05E+07	7,31	**Yes**
	1,00E-05	42		40		42	40			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm}$ * 5)	lg N_a	lg R (lg T_t =7,31)
0,1	1,00E+00	49		47		49	47	2,40E+02	2,38	4,93
	1,00E-01	8		4		<14	<14			
1,0	1,00E+00	2		0		<14	<14	<7,00E+01	< 1,85	≥ 5,47
	1,00E-01	0		0		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
0,1	1,00E+00	1	0	2	5,00	**Yes**
1,0	1,00E+00	0	0	0	0,00	**Yes**

N_W test fields 2-4 (CFU/25 cm²)

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	11	2	133	**Yes**
	1,00E-01	6	2	0		

Table 1.8: Validation, Controls and Evaluation

Product name: **Incidin Active**
Test organism: *Pseudomonas aeruginosa*
Contact time: **5 minutes**

Batch: 1245FM0707
Organic load: dirty conditions
Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			1 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	78		75	V_{c1}	80		81	V_{c1}	82		83
V_{c2}	72			V_{c2}	82			V_{c2}	84		
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0{,}5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is $\geq 0{,}5 \times \bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	$7{,}88 \leq N_{V0} \leq 8{,}40$?
	1,00E-07	>330		>330		>660	>660	3,45E+09	8,19	**Yes**
	1,00E-08	39		30		39	30	9,54		
Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	lg T_0	$6{,}88 \leq T_0 \leq 8{,}40$?
	1,00E-04	>330		>330		>660	>660	2,90E+07	7,46	**Yes**
	1,00E-05	48		68		48	68			
Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	N_0=N/10; lg N_0	$6{,}88 \leq T_t \leq 8{,}40$?
	1,00E-04	>330		>330		>660	>660	2,43E+07	7,38	**Yes**
	1,00E-05	41		56		41	56			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm} * 5$)	lg N_a	lg R (lg T_t =7,38)
0,1	1,00E+00	4		2		<14	<14	<7,00E+01	< 1,85	≥ 5,54
	1,00E-01	0		0		<14	<14			
1,0	1,00E+00	0		0		<14	<14	<7,00E+01	< 1,85	≥ 5,54
	1,00E-01	0		0		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm} * 5$) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
0,1	1,00E+00	1	1	0	3,33	**Yes**
1,0	1,00E+00	0	0	0	0,00	**Yes**

N_W test fields 2-4 (CFU/25 cm²)

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm} * 5$) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	11	2	133	**Yes**
	1,00E-01	6	2	0		

Table 1.9: Validation, Controls and Evaluation

Product name: **Incidin Active** Batch: 1245FM0707
Test organism: *Mycobacterium terrae* Organic load: dirty conditions
Contact time: **1 minute** Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			2 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	72		73	V_{c1}	68		69,5	V_{c1}	77		73
V_{c2}	74			V_{c2}	71			V_{c2}	69		
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	$7,88 \leq N_{V0} \leq 8,40$?
	1,00E-07	>330		>330		>660	>660	3,35E+09	8,18	**Yes**
	1,00E-08	39		28		39	28	9,53		

Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	lg T_0	$6,88 \leq T_0 \leq 8,40$?
	1,00E-04	>330	>330	>330	>330	>660	>660	2,30E+07	7,36	**Yes**
	1,00E-05	14	29	28	21	43	49			

Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	N_0=N/10; lg N_0	$6,88 \leq T_t \leq 8,40$?
	1,00E-04	152	>330	>330	218	>660	>660	1,85E+07	7,27	**Yes**
	1,00E-05	25	15	25	9	40	34			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm} * 5$)	lg N_a	lg R (lg T_t =7,27)
0,2	1,00E+00	>330		>330		>330	>330	>3,30E+04	> 4,22	≤ 2,75
	1,00E-01	>330		>330		>330	>330			
2,0	1,00E+00	24		30		24	30	1,35E+02	2,13	5,14
	1,00E-01	4		4		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm} * 5$) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
0,2	1,00E+00	>330	>330	>330	>1650	No
2,0	1,00E+00	1	17	3	35,00	**Yes**

N_W test fields 2-4 (CFU/25 cm²)

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm} * 5$) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	>16500	**Yes**
	1,00E-01	>330	>330	>330		

Table 1.10: Validation, Controls and Evaluation

Product name: **Incidin Active**
Test organism: *Mycobacterium terrae*
Contact time: **5 minutes**

Batch: 1245FM0707
Organic load: dirty conditions
Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			2 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	72		73	V_{c1}	68		69,5	V_{c1}	77		73
V_{c2}	74			V_{c2}	71			V_{c2}	69		
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	$7,88 \leq N_{V0} \leq 8,40$?
	1,00E-07	>330		>330		>660	>660	3,35E+09	8,18	**Yes**
	1,00E-08	39		28		39	28	9,53		

Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	lg T_0	$6,88 \leq T_0 \leq 8,40$?
	1,00E-04	>330	>330	>330	>330	>660	>660	2,30E+07	7,36	**Yes**
	1,00E-05	14	29	28	21	43	49			

Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	N_0=N/10; lg N_0	$6,88 \leq T_t \leq 8,40$?
	1,00E-04	222	218	186	266	440	452	2,52E+07	7,40	**Yes**
	1,00E-05	46	58	49	65	104	114			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm}$ * 5)	lg N_a	lg R (lg T_t =7,40)
0,2	1,00E+00	>330		>330		>330	>330	>3,30E+04	> 4,22	≤ 2,88
	1,00E-01	>330		>330		>330	>330			
2,0	1,00E+00	0		0		<14	<14	<7,00E+01	< 1,85	≥ 5,56
	1,00E-01	0		0		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
0,2	1,00E+00	>330	>330	>330	>1650	No
2,0	1,00E+00	0	0	0	0,00	**Yes**

N_W test fields 2-4 (CFU/25 cm²)

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	>16500	**Yes**
	1,00E-01	>330	>330	>330		

Table 1.11: Validation, Controls and Evaluation

Product name: **Incidin Active**
Test organism: *Mycobacterium terrae*
Contact time: **5 minutes**

Batch: 1245FM0707
Organic load: dirty conditions
Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			2 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	67	52	114	V_{c1}	60	72	129	V_{c1}	62	56	126
V_{c2}	58	51		V_{c2}	68	58		V_{c2}	66	68	
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0{,}5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is $\geq 0{,}5 \times \bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	$7{,}88 \leq N_{V0} \leq 8{,}40$?
	1,00E-07	>330	>330	>330	>330	>660	>660	5,05E+09	8,36	**Yes**
	1,00E-08	22	25	27	27	47	54	9,70		
Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	lg T_0	$6{,}88 \leq T_0 \leq 8{,}40$?
	1,00E-04	>330	>330	>330	>330	>660	>660	7,10E+07	7,85	**Yes**
	1,00E-05	88	60	84	52	148	136			
Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	N_0=N/10; lg N_0	$6{,}88 \leq T_t \leq 8{,}40$?
	1,00E-04	>330	>330	>330	>330	>660	>660	9,60E+07	7,98	**Yes**
	1,00E-05	98	102	99	85	200	184			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm}$ * 5)	lg N_a	lg R (lg T_t =7,98)
2,0	1,00E+00	5		3		<14	<14	<7,00E+01	< 1,85	≥ 6,14
	1,00E-01	7		1		<14	<14			
2,0	1,00E+00	62		58		62	58	3,00E+02	2,48	5,51
	1,00E-01	10		12		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
2,0	1,00E+00	0	9	1	16,67	**Yes**
2,0	1,00E+00	0	2	1	5,00	**Yes**

N_W test fields 2-4 (CFU/25 cm²)

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	>16500	**Yes**
	1,00E-01	>330	>330	>330		

Table 1.12: Validation, Controls and Evaluation

Product name: **Incidin Active** Batch: 1245FM0707
Test organism: *Mycobacterium avium* Organic load: dirty conditions
Contact time: **1 minute** Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			2 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	28		29,5	V_{c1}	32		32	V_{c1}	30		32
V_{c2}	31			V_{c2}	32			V_{c2}	34		
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	7,88 ≤ N_{V0} ≤ 8,40 ?
	1,00E-07	178		149		178	149	1,67E+09	7,88	**Yes**
	1,00E-08	27		14		27	14	9,22		
Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ * 5	lg T_0	6,88 ≤ T_0 ≤ 8,40 ?
	1,00E-04	80	80	90	130	160	220	9,50E+06	6,98	**Yes**
	1,00E-05	8	8	9	13	16	22			
Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ * 5	N_0=N/10; lg N_0	6,88 ≤ T_t ≤ 8,40 ?
	1,00E-04	140	60	80	180	200	260	1,15E+07	7,06	**Yes**
	1,00E-05	14	6	8	18	20	26			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm}$ * 5)	lg N_a	lg R (lg T_t =7,06)
0,2	1,00E+00	>330		>330		>330	>330	>3,30E+04	> 4,22	≤ 2,54
	1,00E-01	>330		>330		>330	>330			
2,0	1,00E+00	9		4		<14	<14	<7,00E+01	< 1,85	≥ 5,22
	1,00E-01	2		4		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
0,2	1,00E+00	39	46	67	253,33	No
2,0	1,00E+00	0	0	0	0,00	**Yes**

N_W test fields 2-4 (CFU/25 cm²)

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	112	112	106	550	**Yes**
	1,00E-01	10	7	6		

Table 1.13: Validation, Controls and Evaluation

Product name: **Incidin Active** Batch: 1245FM0707
Test organism: *Mycobacterium avium* Organic load: dirty conditions
Contact time: **5 minutes** Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)					Vali. of inactivation (C) at				2 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$		Microbial count			$\bar{x}$	
V_{c1}	28		29,5	V_{c1}	32		32		V_{c1}	30		32	
V_{c2}	31			V_{c2}	32				V_{c2}	34			
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**		$\bar{x}$ of C is $\geq 0,5 \times \bar{x}$ of N_{v0}?				**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	7,88 ≤ N_{V0} ≤ 8,40 ?
	1,00E-07	178		148		178	148	1,67E+09	7,88	**Yes**
	1,00E-08	27		14		27	14	9,22		
Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ * 5	lg T_0	6,88 ≤ T_0 ≤ 8,40 ?
	1,00E-04	80	80	90	130	160	220	9,50E+06	6,98	**Yes**
	1,00E-05	8	8	9	13	16	22			
Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ * 5	N_0=N/10; lg N_0	6,88 ≤ T_t ≤ 8,40 ?
	1,00E-04	52	86	94	90	138	184	8,05E+06	6,91	**Yes**
	1,00E-05	10	20	12	9	30	21			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm}$ * 5)	lg N_a	lg R (lg T_t =6,91)
0,2	1,00E+00	0		0		<14	<14	<7,00E+01	< 1,85	≥ 5,06
	1,00E-01	0		0		<14	<14			
2,0	1,00E+00	2		1		<14	<14	<7,00E+01	< 1,85	≥ 5,06
	1,00E-01	0		0		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
0,2	1,00E+00	1	1	91	155,00	No
2,0	1,00E+00	1	0	1	3,33	**Yes**

N $_W$ **test fields 2-4 (CFU/25 cm²)**

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	112	101	108	535	**Yes**
	1,00E-01	11	7	6		

Table 1.14: Validation, Controls and Evaluation

Product name: **Incidin Active**
Test organism: *Mycobacterium avium*
Contact time: **5 minutes**

Batch: 1245FM0707
Organic load: dirty conditions
Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			2 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	76	42	115	V_{c1}	50	58	116	V_{c1}	76	62	124
V_{c2}	54	58		V_{c2}	64	60		V_{c2}	54	56	
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0{,}5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is $\geq 0{,}5 \times \bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	$7{,}88 \leq N_{V0} \leq 8{,}40$?
	1,00E-07	>330	>330	>330	>330	>660	>660	5,30E+09	8,38	**Yes**
	1,00E-08	24	25	27	30	49	57	9,72		
Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	lg T_0	$6{,}88 \leq T_0 \leq 8{,}40$?
	1,00E-04	>330	>330	>330	>300	>660	>660	4,88E+07	7,69	**Yes**
	1,00E-05	53	38	62	42	91	104			
Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	N_0=N/10; lg N_0	$6{,}88 \leq T_t \leq 8{,}40$?
	1,00E-04	>330	>330	>330	>330	>660	>660	5,80E+07	7,76	**Yes**
	1,00E-05	50	58	64	60	108	124			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm}$ * 5)	lg N_a	lg R (lg T_t =7,76)
2,0	1,00E+00	92		74		92	74	4,15E+02	2,62	5,15
	1,00E-01	1		1		<14	<14			
2,0	1,00E+00	35		27		35	27	1,55E+02	2,19	5,57
	1,00E-01	1		2		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
2,0	1,00E+00	0	0	0	0,00	**Yes**
2,0	1,00E+00	1	0	0	1,67	**Yes**

***N_W* test fields 2-4 (CFU/25 cm²)**

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	>7017	**Yes**
	1,00E-01	>330	52	39		

Table 2.1: Validation, Controls and Evaluation

Product name: **Incidin Active**
Test organism: *Candida albicans*
Contact time: **1 minute**

Batch: 1245FM0707
Organic load: dirty conditions
Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			1 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	32		33,5	V_{c1}	31		29,5	V_{c1}	36		35,5
V_{c2}	35			V_{c2}	28			V_{c2}	35		
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	$6,88 \leq N_{V0} \leq 7,40$?
	1,00E-07	33		28		33	28	3,05E+08	7,14	**Yes**
	1,00E-08	3		1		3	1	8,48		

Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	lg T_0	$5,88 \leq T_0 \leq 7,40$?
	1,00E-03	>330		>330		>660	>660	1,45E+06	6,16	**Yes**
	1,00E-04	30		28		30	28			

Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	N_0=N/10; lg N_0	$5,88 \leq T_t \leq 7,40$?
	1,00E-03	>330		>330		>660	>660	2,18E+06	6,34	**Yes**
	1,00E-04	43		44		43	44			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm}$ * 5)	lg N_a	lg R (lg T_t =6,34)
0,1	1,00E+00	15		7		15	<14	<5,50E+01	> 1,74	> 4,60
	1,00E-01	2		0		<14	<14			
1,0	1,00E+00	0		0		<14	<14	<7,00E+01	< 1,85	≥ 4,49
	1,00E-01	0		0		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
0,1	1,00E+00	3	3	2	13,33	**Yes**
1,0	1,00E+00	0	0	0	0,00	**Yes**

***N_W* test fields 2-4 (CFU/25 cm²)**

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	53	26	6	142	**Yes**
	1,00E-01	4	1	1		

Table 2.2: Validation, Controls and Evaluation

Product name: **Incidin Active**
Test organism: *Candida albicans*
Contact time: **5 minutes**

Batch: 1245FM0707
Organic load: dirty conditions
Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			1 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	32		33,5	V_{c1}	31		29,5	V_{c1}	36		35,5
V_{c2}	35			V_{c2}	28			V_{c2}	35		
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	$6,88 \leq N_{V0} \leq 7,40$?
	1,00E-07	33		28		33	28	3,05E+08	7,14	**Yes**
	1,00E-08	3		1		3	1	8,48		
Control test for drying (D_{C0})	T_0	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	lg T_0	$5,88 \leq T_0 \leq 7,40$?
	1,00E-03	>330		>330		>660	>660	1,45E+06	6,16	**Yes**
	1,00E-04	30		28		30	28			
Control test for drying after t (D_{Ct})	T_t	Microbial count				V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	N_0=N/10; lg N_0	$5,88 \leq T_t \leq 7,40$?
	1,00E-03	>330		>330		>660	>660	1,18E+06	6,07	**Yes**
	1,00E-04	23		24		23	24			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm}$ * 5)	lg N_a	lg R (lg T_t =6,07)
0,1	1,00E+00	3		6		<14	<14	<7,00E+01	< 1,85	≥ 4,22
	1,00E-01	1		2		<14	<14			
1,0	1,00E+00	0		0		<14	<14	<7,00E+01	< 1,85	≥ 4,22
	1,00E-01	0		0		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
0,1	1,00E+00	2	1	1	6,67	**Yes**
1,0	1,00E+00	0	0	0	0,00	**Yes**

***N_W* test fields 2-4 (CFU/25 cm²)**

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm}$ * 5) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	53	26	6	142	**Yes**
	1,00E-01	4	1	1		

Table 2.3: Validation, Controls and Evaluation

Product name: **Incidin Active** Batch: 1245FM0707
Test organism: *Candida albicans* Organic load: dirty conditions
Contact time: **5 minutes** Neutraliser: TLSH-Nt

Suspension for validation (N_{v0})				Control of neutraliser (B)				Vali. of inactivation (C) at			1 %
Microbial count			$\bar{x}$	Microbial count			$\bar{x}$	Microbial count			$\bar{x}$
V_{c1}	32		33,5	V_{c1}	31		29,5	V_{c1}	36		35,5
V_{c2}	35			V_{c2}	28			V_{c2}	35		
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			**Yes**	$\bar{x}$ of B is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**	$\bar{x}$ of C is $\geq 0,5 \times \bar{x}$ of N_{v0}?			**Yes**

Test suspension (N and N_0)	N	Microbial count			V_{c1}	V_{c2}	$\bar{x}_{wm}$ / lg N	N_0=N/22,22; lg N_0	$6,88 \leq N_{V0} \leq 7,40$?
	1,00E-07	51	50		51	50	5,05E+08	7,36	**Yes**
	1,00E-08	4	5		4	5	8,70		
Control test for drying (D_{C0})	T_0	Microbial count			V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	lg T_0	$5,88 \leq T_0 \leq 7,40$?
	1,00E-03	>330	>330		>660	>660	1,50E+06	6,18	**Yes**
	1,00E-04	20	40		20	40			
Control test for drying after t (D_{Ct})	T_t	Microbial count			V_{c1}	V_{c2}	$\bar{x}_{wm} * 5$	N_0=N/10; lg N_0	$5,88 \leq T_t \leq 7,40$?
	1,00E-03	>330	>330		>660	>660	8,25E+05	5,92	**Yes**
	1,00E-04	13	20		13	20			

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count			V_{c1}	V_{c2}	N_a (= $\bar{x}$ or $\bar{x}_{wm} * 5$)	lg N_a	lg R (lg T_t =5,92)
1,0	1,00E+00	0	0		<14	<14	<7,00E+01	< 1,85	≥ 4,07
	1,00E-01	0	0		<14	<14			
1,0	1,00E+00	0	0		<14	<14	<7,00E+01	< 1,85	≥ 4,07
	1,00E-01	0	0		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			V_{T2to4} (= $\bar{x}$ or $\bar{x}_{wm} * 5$) CFU/25 cm²	V_{T2to4} <50 KBE/25cm²
		$V_C T_2$	$V_C T_3$	$V_C T_4$		
1,0	1,00E+00	0	0	0	0,00	**Yes**
1,0	1,00E+00	0	0	0	0,00	**Yes**

***N_w* test fields 2-4 (CFU/25 cm²)**

Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2to4}$ (= $\bar{x}$ or $\bar{x}_{wm} * 5$) CFU/25 cm²	V_{T2to4} >10 KBE/25cm²
		T_2	T_3	T_4		
0,00	1,00E+00	6	4	2	20	**Yes**
	1,00E-01	2	1	0		

4 List of Abbreviations

A	=	control of test conditions
B	=	control of neutraliser
C	=	validation of method at highest product concentration
N	=	test suspension
N_{V0}	=	suspension for validation
n.t.	=	not tested
N_0	=	microbial count of test suspension N / 10 (microbial count at time index 0)
R	=	germ reduction in log_{10}-steps
V_C	=	viable microbial count per ml
$\bar{x}$	=	weighted mean of N