

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



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

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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:	<i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541 <i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Candida albicans</i> ATCC 10231 <i>Mycobacterium terrae</i> ATCC 15755 <i>Mycobacterium avium</i> ATCC 15769

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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 \geq 5; Candida, Mycobacteria RF \geq 4) inactivated with the following concentration-time relationship:

Bactericidal:	dirty conditions	1.0 %	5 minutes
Yeasticidal:	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

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Table 1.1: Summary of two test runs

Test organism	Contact time [min]	product concentration [%]	Field 1			Field 2-4			Wipe control Field 2-4	
			log Reduction			CFU/25cm ²			CFU/25cm ²	
			1	2	3	1	2	3	1	2+3
<i>S. aureus</i>	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	
<i>E. hirae</i>	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	
<i>P. aeruginosa</i>	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	
<i>M. terrae</i>	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	
<i>M. avium</i>	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	
<i>C. albicans</i>	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	

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Table 1.2: Validation, Controls and Evaluation

Product name: **Incidin Active** Batch: 1245FM0707
Test organism: *Staphylococcus aureus* 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 1 %			
Microbial count			Microbial count				Microbial count			
V_{c1}	77	75	V_{c1}	72	69,5		V_{c1}	78	75,5	
V_{c2}	73		V_{c2}	67			V_{c2}	73		
$30 \leq \bar{x} \text{ of } N_{v0} \leq 160$			Yes				$\bar{x} \text{ of B is } \geq 0,5 \times \bar{x} \text{ of } N_{v0}?$			
Yes			Yes				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	4,40E+07	7,64	Yes		
	1,00E-05	86	90	86	90					

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	$N_a (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$\lg N_a$	$\lg R$
		$\lg R$								
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	$\geq 5,80$		
	1,00E-01	0	0	<14	<14					

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			$V_{T2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2to4} < 50$ KBE/25cm ²
		V_{cT2}	V_{cT3}	V_{cT4}		
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			$V_{NWT2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2to4} > 10$ KBE/25cm ²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	>16500	Yes
	1,00E-01	>330	>330	>330		

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Table 1.3: Validation, Controls and Evaluation

Product name: **Incidin Active** Batch: 1245FM0707
 Test organism: *Staphylococcus aureus* 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			Microbial count				Microbial count			
V_{c1}	77	75	V_{c1}	72	69,5		V_{c1}	78	75,5	
V_{c2}	73		V_{c2}	67			V_{c2}	73		
$30 \leq \bar{x} \text{ of } N_{v0} \leq 160$		Yes	$\bar{x} \text{ of B is } \geq 0,5 \times \bar{x} \text{ of } N_{v0}?$		Yes		$\bar{x} \text{ of C is } \geq 0,5 \times \bar{x} \text{ of } N_{v0}?$		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}	$N_a (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$\lg N_a$	$\lg R$
										$(\lg T_t = 7,68)$
0,1	1,00E+00	2	4	<14	<14	<7,00E+01	<1,85	$\geq 5,83$		
	1,00E-01	0	0	<14	<14					
1,0	1,00E+00	10	15	<14	15	<7,00E+01	<1,85	$\geq 5,83$		
	1,00E-01	0	0	<14	<14					

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			$V_{T2t04} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2t04} < 50$ KBE/25cm ²
		V_{cT2}	V_{cT3}	V_{cT4}		
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			$V_{NWT2t04} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2t04} > 10$ KBE/25cm ²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	>16500	Yes
	1,00E-01	>330	>330	>330		

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Table 1.4: Validation, Controls and Evaluation

Product name: **Incidin Active** Batch: 1245FM0707
Test organism: *Enterococcus hirae* 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 1 %			
Microbial count			Microbial count				Microbial count			
V_{c1}	97	94,5	V_{c1}	89	90	V_{c1}	94	94		
V_{c2}	92		V_{c2}	91		V_{c2}	94			
$30 \leq \bar{x} \text{ of } N_{V0} \leq 160$		Yes	$\bar{x} \text{ of B is } \geq 0,5 \times \bar{x} \text{ of } N_{V0}?$		Yes	$\bar{x} \text{ of C is } \geq 0,5 \times \bar{x} \text{ of } N_{V0}?$		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}	$N_a (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$\lg N_a$	$\lg R$
		V_{cT2}	V_{cT3}	V_{cT4}	$(\lg T_t = 7,59)$					
0,1	1,00E+00	>330	>330	>330	>330	>330	>3,30E+04	> 4,22	$\leq 3,07$	
	1,00E-01	>330	>330	>330	>330	>330				
1,0	1,00E+00	10	14	<14	<14	<7,00E+01	< 1,85	$\geq 5,75$		
	1,00E-01	0	0	<14	<14					

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			$V_{T2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2to4} < 50$ KBE/25cm ²
		V_{cT2}	V_{cT3}	V_{cT4}		
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			$V_{NWT2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2to4} > 10$ KBE/25cm ²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	1983	Yes
	1,00E-01	21	51	47		

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Table 1.5: Validation, Controls and Evaluation

Product name: **Incidin Active** Batch: 1245FM0707
Test organism: *Enterococcus hirae* 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			Microbial count				Microbial count			
V_{c1}	97	94,5	V_{c1}	89	90		V_{c1}	94	94	
V_{c2}	92		V_{c2}	91			V_{c2}	94		
$30 \leq \bar{x} \text{ of } N_{v0} \leq 160$			Yes				$\bar{x} \text{ of C is } \geq 0,5 \times \bar{x} \text{ of } N_{v0}?$			
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	3,85E+07	7,59	Yes		
	1,00E-05	80	74	80	74					

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	$N_a (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$\lg N_a$	$\lg R$
		V_{c1}	V_{c2}	V_{c1}	V_{c2}					$(\lg T_t = 7,59)$
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	$\geq 5,74$		
	1,00E-01	0	0	<14	<14					

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			$V_{T2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2to4} < 50$ KBE/25cm ²
		V_{cT_2}	V_{cT_3}	V_{cT_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			$V_{NWT2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2to4} > 10$ KBE/25cm ²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	1983	Yes
	1,00E-01	21	51	47		

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Table 1.6: Validation, Controls and Evaluation

Product name: **Incidin Active** Batch: 1245FM0707
Test organism: *Enterococcus hirae* 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			Microbial count				Microbial count		
V_{c1}	64		V_{c1}	70		V_{c1}	45		
V_{c2}	60		V_{c2}	60		V_{c2}	64		
62			65				54,5		
$30 \leq \bar{x} \text{ of } N_{v0} \leq 160$			$\bar{x} \text{ of B is } \geq 0,5 \times \bar{x} \text{ of } N_{v0}?$				$\bar{x} \text{ of C is } \geq 0,5 \times \bar{x} \text{ of } N_{v0}?$		
Yes			Yes				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	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}	$\bar{x}_{wm} * 5$	$\lg T_0$	$6,88 \leq T_0 \leq 8,40?$
	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}	$\bar{x}_{wm} * 5$	$N_0=N/10; \lg N_0$	$6,88 \leq T_t \leq 8,40?$
	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}	$N_a (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$\lg N_a$	$\lg R$
										$(\lg T_t = 7,39)$
1,0	1,00E+00	0		2		<14	<14	<7,00E+01	< 1,85	$\geq 5,54$
	1,00E-01	0		0		<14	<14			
1,0	1,00E+00	0		0		<14	<14	<7,00E+01	< 1,85	$\geq 5,54$
	1,00E-01	0		0		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			$V_{T2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2to4} < 50$ KBE/25cm ²
		V_{cT_2}	V_{cT_3}	V_{cT_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			$V_{NWT2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2to4} > 10$ KBE/25cm ²
		T_2	T_3	T_4		
0,00	1,00E+00	7	0	0	12	Yes
	1,00E-01	0	0	0		

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Table 1.7: Validation, Controls and Evaluation

Product name: **Incidin Active** Batch: 1245FM0707
Test organism: *Pseudomonas aeruginosa* 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 1 %				
Microbial count		\bar{x}		Microbial count		\bar{x}				
V_{c1}	78	75		V_{c1}	80	V_{c1}	82			
V_{c2}	72			V_{c2}	82	V_{c2}	84			
$30 \leq \bar{x} \text{ of } N_{V0} \leq 160$		Yes		$\bar{x} \text{ of B is } \geq 0,5 \times \bar{x} \text{ of } N_{V0}?$		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	2,05E+07	7,31	Yes		
	1,00E-05	42	40	42	40					

Test field 1 (Reduction)

Product-concentration [%]	Dilution	Microbial count				V_{c1}	V_{c2}	$N_a (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$\lg N_a$	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	$\geq 5,47$		
	1,00E-01	0	0	<14	<14					

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			$V_{T2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2to4} < 50$ KBE/25cm ²
		V_{cT2}	V_{cT3}	V_{cT4}		
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			$V_{NWT2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2to4} > 10$ KBE/25cm ²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	11	2	133	Yes
	1,00E-01	6	2	0		

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Table 1.8: Validation, Controls and Evaluation

Product name: **Incidin Active** Batch: 1245FM0707
Test organism: *Pseudomonas aeruginosa* 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			Microbial count				Microbial count			
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 $N_{V0} \leq 160$			\bar{x} of B is $\geq 0,5 \times \bar{x}$ of N_{V0} ?				\bar{x} of C is $\geq 0,5 \times \bar{x}$ of N_{V0} ?			
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	$\geq 5,54$		
	1,00E-01	0	0	<14	<14					
1,0	1,00E+00	0	0	<14	<14	<7,00E+01	<1,85	$\geq 5,54$		
	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 cm ²	$V_{T2to4} < 50$ KBE/25cm ²
		V_{cT_2}	V_{cT_3}	V_{cT_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 cm ²	$V_{T2to4} > 10$ KBE/25cm ²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	11	2	133	Yes
	1,00E-01	6	2	0		

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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			Microbial count				Microbial count		
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 $N_{v0} \leq 160$			\bar{x} of B is $\geq 0,5 \times \bar{x}$ of N_{v0} ?				\bar{x} of C is $\geq 0,5 \times \bar{x}$ of N_{v0} ?		
		Yes		Yes		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	3,35E+09	8,18	Yes
	1,00E-08	39	28	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 $\bar{x}_{wm} * 5)$	$\lg N_a$	$\lg R$
		$\lg R$								
0,2	1,00E+00	>330	>330	>330	>330	>330	>3,30E+04	> 4,22	$\leq 2,75$	
	1,00E-01	>330	>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 cm ²	$V_{T2to4} < 50$ KBE/25cm ²
		V_{cT2}	V_{cT3}	V_{cT4}		
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 cm ²	$V_{T2to4} > 10$ KBE/25cm ²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	>16500	Yes
	1,00E-01	>330	>330	>330		

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Table 1.10: Validation, Controls and Evaluation

Product name: **Incidin Active** Batch: 1245FM0707
Test organism: *Mycobacterium terrae* 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			Microbial count				Microbial count			
V_{c1}	72		V_{c1}	68		V_{c1}	77			
V_{c2}	74		V_{c2}	71		V_{c2}	69			
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			\bar{x} of B is $\geq 0,5 \times \bar{x}$ of N_{v0} ?				\bar{x} of C is $\geq 0,5 \times \bar{x}$ of N_{v0} ?			
Yes			Yes				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	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}	$N_a (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$\lg N_a$	$\lg R$
										$(\lg T_t = 7,40)$
0,2	1,00E+00	>330	>330	>330	>330	>330	>330	>3,30E+04	> 4,22	$\leq 2,88$
	1,00E-01	>330	>330	>330	>330	>330	>330			
2,0	1,00E+00	0	0	<14	<14	<14	<14	<7,00E+01	< 1,85	$\geq 5,56$
	1,00E-01	0	0	<14	<14	<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			$V_{T2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$V_{T2to4} < 50$
		V_{cT_2}	V_{cT_3}	V_{cT_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			$V_{NWT2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$V_{T2to4} > 10$
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	>16500	Yes
	1,00E-01	>330	>330	>330		

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Table 1.11: Validation, Controls and Evaluation

Product name: **Incidin Active** Batch: 1245FM0707
Test organism: *Mycobacterium terrae* 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			Microbial count				Microbial count				
V_{c1}	67	52	V_{c1}	60	72	V_{c1}	62	56			
V_{c2}	58	51	V_{c2}	68	58	V_{c2}	66	68			
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			\bar{x} of B is $\geq 0,5 \times \bar{x}$ of N_{v0} ?				\bar{x} of C is $\geq 0,5 \times \bar{x}$ of N_{v0} ?				
Yes			Yes				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	$\geq 6,14$
	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 $\bar{x}_{wm} * 5)$	$V_{T2to4} < 50$
		V_{cT2}	V_{cT3}	V_{cT4}		
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 $\bar{x}_{wm} * 5)$	$V_{T2to4} > 10$
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	>16500	Yes
	1,00E-01	>330	>330	>330		

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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			Microbial count				Microbial count			
V_{c1}	28	29,5	V_{c1}	32	32		V_{c1}	30	32	
V_{c2}	31		V_{c2}	32			V_{c2}	34		
$30 \leq \bar{x} \text{ of } N_{v0} \leq 160$		Yes	$\bar{x} \text{ of B is } \geq 0,5 \times \bar{x} \text{ of } N_{v0}?$		Yes		$\bar{x} \text{ of C is } \geq 0,5 \times \bar{x} \text{ of } N_{v0}?$		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	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}	$\bar{x}_{wm} * 5$	$\lg T_0$	$6,88 \leq T_0 \leq 8,40 ?$
	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}	$\bar{x}_{wm} * 5$	$N_0=N/10; \lg N_0$	$6,88 \leq T_t \leq 8,40 ?$
	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}	$N_a (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$\lg N_a$	$\lg R$
										$(\lg T_t = 7,06)$
0,2	1,00E+00	>330		>330		>330	>330	>3,30E+04	> 4,22	$\leq 2,54$
	1,00E-01	>330		>330		>330	>330			
2,0	1,00E+00	9		4		<14	<14	<7,00E+01	< 1,85	$\geq 5,22$
	1,00E-01	2		4		<14	<14			

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			$V_{T2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2to4} < 50$ KBE/25cm ²
		V_{cT_2}	V_{cT_3}	V_{cT_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			$V_{NWT2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2to4} > 10$ KBE/25cm ²
		T_2	T_3	T_4		
0,00	1,00E+00	112	112	106	550	Yes
	1,00E-01	10	7	6		

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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			Microbial count				Microbial count			
V_{c1}	28	29,5	V_{c1}	32	32		V_{c1}	30	32	
V_{c2}	31		V_{c2}	32			V_{c2}	34		
$30 \leq \bar{x} \text{ of } N_{v0} \leq 160$			Yes	$\bar{x} \text{ of B is } \geq 0,5 \times \bar{x} \text{ of } N_{v0}?$			Yes	$\bar{x} \text{ of C is } \geq 0,5 \times \bar{x} \text{ of } N_{v0}?$		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	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}	$\bar{x}_{wm} * 5$	$\lg T_0$	$6,88 \leq T_0 \leq 8,40?$
	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}	$\bar{x}_{wm} * 5$	$N_0 = N/10; \lg N_0$	$6,88 \leq T_t \leq 8,40?$
	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}	$N_a (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$\lg N_a$	$\lg R$ ($\lg T_t = 6,91$)
0,2	1,00E+00	0	0	0	<14	<14	<7,00E+01	< 1,85	$\geq 5,06$	
	1,00E-01	0	0	0	<14	<14				
2,0	1,00E+00	2	1	0	<14	<14	<7,00E+01	< 1,85	$\geq 5,06$	
	1,00E-01	0	0	0	<14	<14				
Test fields 2-4 (CFU/25 cm²)										
Product concentration [%]	Dilution	Microbial count on test fields			$V_{T2t04} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$V_{T2t04} < 50$				
		V_{cT_2}	V_{cT_3}	V_{cT_4}	CFU/25 cm ²	KBE/25cm ²				
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			$V_{NWT2t04} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$V_{T2t04} > 10$				
		T_2	T_3	T_4	CFU/25 cm ²	KBE/25cm ²				
0,00	1,00E+00	112	101	108	535	Yes				
	1,00E-01	11	7	6						

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Table 1.14: 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			Microbial count				Microbial count			
V_{c1}	76	42	V_{c1} 50 58 V_{c2} 64 60				V_{c1}	76	62	
V_{c2}	54	58					V_{c1}	76	62	
$30 \leq \bar{x}$ of $N_{v0} \leq 160$			\bar{x} of B is $\geq 0,5 \times \bar{x}$ of N_{v0} ?				\bar{x} of C is $\geq 0,5 \times \bar{x}$ of N_{v0} ?			
Yes			Yes				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}	$N_a (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$\lg N_a$	$\lg R$
										$(\lg T_t = 7,76)$
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			$V_{T2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2to4} < 50$ KBE/25cm ²
		V_{cT_2}	V_{cT_3}	V_{cT_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			$V_{NWT2to4} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2to4} > 10$ KBE/25cm ²
		T_2	T_3	T_4		
0,00	1,00E+00	>330	>330	>330	>7017	Yes
	1,00E-01	>330	52	39		

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Table 2.1: Validation, Controls and Evaluation

Product name: **Incidin Active** Batch: 1245FM0707
Test organism: *Candida albicans* 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 1 %			
Microbial count			Microbial count				Microbial count			
V_{c1}	32	33,5	V_{c1}	31	29,5		V_{c1}	36	35,5	
V_{c2}	35		V_{c2}	28			V_{c2}	35		
$30 \leq \bar{x} \text{ of } N_{v0} \leq 160$			$\bar{x} \text{ of B is } \geq 0,5 \times \bar{x} \text{ of } N_{v0}?$				$\bar{x} \text{ of C is } \geq 0,5 \times \bar{x} \text{ of } N_{v0}?$			
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}	$N_a (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$\lg N_a$	$\lg R$
									$(\lg T_t = 6,34)$
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	$\geq 4,49$	
	1,00E-01	0	0	<14	<14				

Test fields 2-4 (CFU/25 cm²)

Product concentration [%]	Dilution	Microbial count on test fields			$V_{T2t04} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2t04} < 50$ KBE/25cm ²
		V_{cT_2}	V_{cT_3}	V_{cT_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			$V_{NWT2t04} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$ CFU/25 cm ²	$V_{T2t04} > 10$ KBE/25cm ²
		T_2	T_3	T_4		
0,00	1,00E+00	53	26	6	142	Yes
	1,00E-01	4	1	1		

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Table 2.2: 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			Microbial count				Microbial count			
\bar{x}			\bar{x}				\bar{x}			
V_{c1}	32		V_{c1}	31		V_{c1}	36			
V_{c2}	35		V_{c2}	28		V_{c2}	35			
33,5			29,5				35,5			
$30 \leq \bar{x} \text{ of } N_{v0} \leq 160$			$\bar{x} \text{ of B is } \geq 0,5 \times \bar{x} \text{ of } N_{v0}?$				$\bar{x} \text{ of C is } \geq 0,5 \times \bar{x} \text{ of } N_{v0}?$			
Yes			Yes				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}	$N_a (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$	$\lg N_a$	$\lg R$ ($\lg T_t = 6,07$)
0,1	1,00E+00	3		6		<14	<14	<7,00E+01	< 1,85	$\geq 4,22$
	1,00E-01	1		2		<14	<14			
1,0	1,00E+00	0		0		<14	<14	<7,00E+01	< 1,85	$\geq 4,22$
	1,00E-01	0		0		<14	<14			
Test fields 2-4 (CFU/25 cm ²)										
Product concentration [%]	Dilution	Microbial count on test fields			$V_{T2t04} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$		$V_{T2t04} < 50$			
		V_{cT_2}	V_{cT_3}	V_{cT_4}	CFU/25 cm ²		KBE/25cm ²			
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 cm ²)										
Product-concentration [%]	Dilution	Microbial count on test fields			$V_{NWT2t04} (= \bar{x} \text{ or } \bar{x}_{wm} * 5)$		$V_{T2t04} > 10$			
		T_2	T_3	T_4	CFU/25 cm ²		KBE/25cm ²			
0,00	1,00E+00	53	26	6	142		Yes			
	1,00E-01	4	1	1						

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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			Microbial count				Microbial count		
V _{c1}	32		V _{c1}	31		V _{c1}	36		
V _{c2}	35		V _{c2}	28		V _{c2}	35		
33,5			29,5				35,5		
30 ≤ \bar{x} of N _{v0} ≤ 160			\bar{x} of B is ≥ 0,5 x \bar{x} of N _{v0} ?				\bar{x} of C is ≥ 0,5 x \bar{x} of N _{v0} ?		
Yes			Yes				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 ≤ N _{v0} ≤ 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 ≤ T ₀ ≤ 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 ≤ T _t ≤ 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 cm ²	V _{T2to4} <50 KBE/25cm ²
		V _{cT2}	V _{cT3}	V _{cT4}		
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 cm ²	V _{T2to4} >10 KBE/25cm ²
		T ₂	T ₃	T ₄		
0,00	1,00E+00	6	4	2	20	Yes
	1,00E-01	2	1	0		

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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 _{vo}	=	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

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