HYGIENE NORD GMBH
C/O BIOTECHNIKUM
WALTHER-RATHENAU-STRAßE 49 A
D-17489 GREIFSWALD

EN ISO/IEC 17025 Akkreditierung
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D-PL-18411-01-01
D-PL-18411-01-02

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KAF GRUP SAĞLIK HİZMETLERİ İNŞ.
SAN. VE TİC. LTD. ŞTİ.
Atakent Mah. 221 Sk. No:3A Rota Office
A Blok Kat:14 D:82-83
34307 K.ÇEKMECE / İSTANBUL
Türkei / Turkiye

Digitally signed by Granaci Boris
Date: 2025.09.11 10:48:51 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

CUSTOMER NUMBER	DATE
2503	March 31, 2025

REPORT 250704.V3

ONESPRAY ALCOHOL BASED FAST ACTING SPRAY DISINFECTANT FOR MEDICAL EQUIPMENT

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ONESPRAY WIPES ALCOHOL BASED FAST ACTING DISINFECTANT WIPES FOR MEDICAL DEVICES

YEASTICIDAL ACTIVITY AGAINST *CANDIDA AURIS*
EN 13624 (2021)

This **version 03** of the report replaces the Hygiene Nord GmbH test report 250707.V2, Version 02, dated March 19, 2025, and corrects mistakes in one of the product names on page 2.
The efficacy claim remains unchanged.

Purpose

The yeasticidal activity of the surface disinfectant **ONESPRAY Wipes Alcohol Based Fast Acting Disinfectant Wipes for Medical Devices** (KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. VE TİC. LTD. ŞTİ., Istanbul, Turkey) should be evaluated in accordance with the European Standard **EN 13624 (2021)** against the test organism *C. auris*.

The test product **ONESPRAY Alcohol Based Fast Acting Spray Disinfectant for Medical Equipment** is the soaking liquid of the surface disinfection wipes **ONESPRAY Wipes Alcohol Based Fast Acting Disinfectant Wipes for Medical Devices**. Extraction of that liquid directly from the wipes provided did not produce a sufficiently high volumen for the EN 13624 quantitative suspension tests presented herein. Therefore, these tests were directly performed with the soaking liquid **ONESPRAY Alcohol Based Fast Acting Spray Disinfectant for Medical Equipment**.

sign-me
Signiert von Torsten Koburger-Janssen
am 31.03.2025

HYGIENE NORD GMBH
W.-RATHENAU-STR.49A
17489 GREIFSWALD
DEUTSCHLAND - GERMANY
TELEFON: +49(0)3834-515520
TELEFAX: +49(0)3834-515525
INTERNET: http://www.hygiene-nord.de
E-MAIL: info@hygiene-nord.de
GESCHÄFTSFÜHRER: DR. TORSTEN KOBURGER-JANSSEN
BANK: UNICREDIT-DE
BIC: HYVEDEMMXXX
IBAN: DE44 7002 0270 0045 1616 76
MAG. MARCELLO NICOLOSO
UMSATZSTEUER-ID (VAT / TAX): DE211580653
SITZ DER GESELLSCHAFT: GREIFSWALD
HANDELSREGISTER AMTSGERICHT STRALSUND HRB 5168

Test description

Order number:	A25-0216	
Manufacturer:	KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. VE TİC. LTD. ŞTİ., Istanbul, Turkey	
Product:	**ONESPRAY Wipes Alcohol Based Fast Acting Disinfectant Wipes for Medical Equipment**	**ONESPRAY Alcohol Based Fast Acting Spray Disinfectant for Medical Equipment**
Batch number:	ONCR25013001	0NCR25013001
Sample number:	P251299	P251298
Date of manufacture:	30.01.2025	30.01.2025
Best before:	30.01.2027	30.01.2027
Date of order:	February 06, 2025	February 06, 2025
Date of delivery:	February 06, 2025	February 06, 2025
Storage condition:	room temperature	room temperature
pH – value (pH-meter):	-	100 %: 5.71 80 %: 5.40 50 %: 5.00 10 %: 4.74 WFI: 5.70
Diluent:	water for injections	
Test date:	February 14, 2025 – March 05, 2025	
Basis:	**EN 13624 (2021: Version 08/2022)**: Chemical disinfectants and antiseptics – quantitative suspension test for the evaluation of fungicidal or yeasticidal in the medical area – test method and requirements (phase 2, step 1)	
Test organism[1]:	*Candida auris* DSM 21092	
Test solutions:	97 %, 80 %, 40 %, 10 %, 1 % and 0.1 %	
Active ingredients [1]:	30 % Ethanol, 10 % 2-Propanol 0.25 % Didecylmethylpoly(oxethyl) Ammonium Propionate	
Odour:	product specific	
Appearance of powder:	clear, colourless liquid	
Appearance of dilutions:	clear, colourless liquids	
Neutralizer:	4 % Tween 80 + 3 % Saponin + 0.4 % Lecithin + 0.25 % SDS (neutralizer XXIV)	
Contact time(s):	30 s	
Interfering substance:	0.03 % albumin (clean conditions)	
Test temperature:	20 ± 1 °C	
Incubation temperature:	30 ± 1 °C	
Nutrient medium:	yeast extract agar	

Test Method

Testing is based on the European Standard **EN 13624 (2021)**. Validation and control procedures are therefore carried out in accordance with this standard, too.

In deviation to the EN 13624 standard strains and in accordance to the costumer´s request the yeast *Candida auris* is used as test strain.

For the test, to a sample of the product **ONESPRAY Alcohol Based Fast Acting Spray Disinfectant for Medical Equipment** (diluted with water for injections) is added to a suspension of test organisms in a solution of the interfering substance. The mixture is maintained at 20±1 °C for the required contact time. At the end of the contact time, an aliquot of 1 ml is taken; the microbicidal activity in this portion is immediately neutralized. Two 1 ml samples (per dilution step) of the resulting suspension are spread on at least 2 plates each. The number of surviving test organisms in the test mixture is calculated for each sample and the reduction is determined with respect to the corresponding test suspension N_0.

The experimental conditions (control A), the non-toxicity of the neutralizer (control B) and the dilution-neutralization method (control C) are validated in accordance with the EN 13624. The test is performed under clean conditions (0.03 % albumin). Results are presented in table 1 – 2.

Results and conclusion[2]

In accordance with the **EN 13624 (2021)**, the batch ONCR25013001 of the test product **ONESPRAY Wipes Alcohol Based Fast Acting Disinfectant Wipes for Medical Equipment / ONESPRAY Alcohol Based Fast Acting Spray Disinfectant for Medical Equipment**, when applied at the concentration / contact time - relation of at least **50 % / 30 s** at 20±1 °C under clean conditions (0.03 % albumin), **possesses** yeasticidal efficacy ($\log_{10}$ RF $\geq$ 4) for the reference strain *C. auris* (Tab. 1 - 2).

Results are considered validated in accordance with the requirements of the **EN 13624 (2021).**

Greifswald, March 31, 2025

AKKREDITIERTES PRÜFLABOR
HYGIENE NORD GMBH
W.-RATHENAU-STR. 49A
17489 GREIFSWALD
NACH DIN EN ISO/IEC 17025

Dr. rer med. (Dipl. Biol.) T. Koburger-Janssen — Prof. Dr. med. A. Kramer

- General Manager - — - MD for Hygiene and Environmental Medicine -

Table 1: Results of the quantitative suspension test according to EN 13624 (2021)

Date:	February 21, 2025	**Order number:**	A25-0216
Product:	**ONESPRAY Alcohol Based Fast Acting Spray Disinfectant for Medical Equipment**	**Sample number:**	P251298
Test organism:	*C. auris*	**Batch number:**	0NCR25013001
Interfering substance:	0.03 % albumin		
Incubation temperature:	30 ± 1 °C	**Neutralizer:**	XXIV
Test suspension (N_0):	$4.61*10^6$ cfu/ml (6.66 log)	**Incubation time:**	72 h
Validation Suspension (N_V):	$1.12*10^4$ cfu/ml (4.05 log)	**Test temperature:**	20 ± 1 °C
Validation Suspension (N_{VB}):	$1.36*10^5$ cfu/ml (5.13 log)		

Test suspension (N):	**dilution**	**V_{C1}**	**V_{C2}**	**N (cfu /ml)**	**$\log_{10}$ (N)**
N ≥ $1.5x10^7$≤ $5.0x10^7$ cfu/ml?	0.1 ml 10^{-3}	330	330		
☒ yes ☐ no	0.1 ml 10^{-4}	450	435	**4.61E+07**	**7.66**
	0.1 ml 10^{-5}	63	67		

contact time: 30 s

concentration	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**$\log_{10}$ Na**	**$\log_{10}$ R**
80 %	1 ml (10^0)	0	0	0	0	< 14	< 14	< 2.15	**> 4.52**
	1 ml (10^{-1})	5	2	3	4	< 14	< 14		
50 %	1 ml (10^0)	3	1	2	2	< 14	< 14	< 2.15	**> 4.52**
	1 ml (10^{-1})	0	0	0	0	< 14	< 14		
10 %	1 ml (10^0)	51	23	35	45	74	80	3.02	**3.64**
	1 ml (10^{-1})	22	20	18	16	42	34		

Controls and validation:

Validation - Suspension (N_{VO})					**Experimental condition control (A)**					**Neutralizer control (B)**					**Method validation (C) Product concentration: 80 %**				
	cfu /plate 1 & 2		V_c	$\bar{x}$		cfu /plate 1 & 2		V_c	$\bar{x}$		cfu /plate 1 & 2		V_c	$\bar{x}$		cfu /plate 1 & 2		V_c	$\bar{x}$
V_{c1}	83	77	160	**152.5**	V_{c1}	81	71	152	**151**	V_{c1}	81	76	157	**154.5**	V_{c1}	88	75	163	**161.5**
V_{c2}	70	75	145		V_{c2}	73	77	150		V_{c2}	74	78	152		V_{c2}	78	82	160	
30 ≤ $\bar{x}$ of N_{VO} ≤ 160?					$\bar{x}$ of A is ≥ 0.5 $\bar{x}$ of N_{VO}?					$\bar{x}$ of B is ≥ 0.0005 $\bar{x}$ of N_{VB}?					$\bar{x}$ of C is ≥ 0.5 $\bar{x}$ of N_{VO}?				
X yes			☐ no		X yes			☐ no		X yes			☐ no		X yes			☐ no	

Legend:

[1]	=	as provided by the sponsor / manufacturer (unless stated otherwise)
[2]	=	According to EN 17025, § 7.8.2.1 l, we are required to state that the results presented in this report relate to the item(s) tested only. That is quite obvious in the first place, anyway. And it is also ridiculous, of course, with regard to these tests and reports typically being used for a product's generalized efficacy evaluation and market authorization. Which, as such, is then fully acceptable by all other relevant authorizing and responsible parties (other than EN 17025), too. Which therefore is why this disclaimer is only to be found at the very back end of this report.
$\bar{x}$	=	average value
RF	=	reduction factor
> 330	=	not countable
> 660	=	not countable
n.a.	=	not applicable
n.d.	=	not determined
n.p.	=	not provided
WFI	=	water for injections
WSH	=	water of standardized hardness