

30.05.2024

Subject: Mikrobiological Analysis**To Whom Concern,**

As Kaf Grup Sağlık Hizmetleri İnş. San. And Tic. Ltd., Class IIA, OneSpray Alcohol Based Fast Acting Spray Disinfectant for Medical Equipment, OneSpray Wipes Alcohol Based Fast Acting Disinfectant / Wipes for Medical Devices, OneSurface Alcohol Free Fast Acting Spray Disinfectant for Medical Equipment, Onesurface Wipes Alcohol Free Fast Acting Disinfectant / Wipes for Medical Devices are produced.

Kaf Grup Sağlık Hizmetleri İnş. San. Ve Tic. Ltd. Şti. olarak Sınıf IIA olan OneSpray Tıbbi Ekipmanlar için Alkol Bazlı Hızlı Etkili Sprey Dezenfektan, OneSpray Wipes Tıbbi Cihazlar İçin Alkol Bazlı Hızlı Etkili Dezenfektan/Mendil, OneSurface Tıbbi Ekipmanlar için Alkolsüz Hızlı Etkili Sprey Dezenfektan, Onesurface Wipes Tıbbi Cihazlar İçin Alkolsüz Hızlı Etkili Dezenfektan/Mendil ürünlerimiz üretilmektedir.

Our disinfectant solutions are used for cleaning and disinfection of surgical and medical devices, microsurgical instruments, laboratory equipment, endoscopic equipment used in the medical and dental field, disinfection of hard-to-reach medical device surfaces in sterile areas such as operating theatres with ambient and air disinfection. Our products are used for disinfection of pre-cleaned medical devices (ultrasound probes, etc.) with non-invasive, smooth, smooth and non-porous surfaces that cannot be disinfected by immersion method.

Ürünlerimiz dezenfektan solüsyonları, medikal ve dental alanda kullanılan cerrahi ve tıbbi cihazların, mikro cerrahi aletlerinin, laboratuvar ekipmanları, endoskopik ekipmanların temizliği ve dezenfeksiyonu, ameliyathane gibi steril alanlardaki ulaşılması zor tıbbi cihaz yüzeylerinin ortam ve hava dezenfeksiyonu ile dezenfeksiyonunda kullanılır. Ürünlerimiz ön temizliği yapılmış, daldırma yöntemiyle dezenfeksiyonu mümkün olmayan, non-invaziv, düzgün, pürüzsüz ve gözeneksiz yüzeye sahip tıbbi cihazların (Ultrason problemleri vb.) dezenfeksiyonunda kullanılır.

It has a wide spectrum of action against microorganisms as Bactericide, Fungicide, Virucide, Tuberculocide and Mycobactericide.

Mikroorganizmalara karşı, Bakterisid, Fungusid, Virüs, Tüberkülosid ve Mikobakterisid olarak geniş etki spektrumuna sahiptir.

For our products, the required tests for Chemical disinfectants and antiseptics used in medical device disinfection have been completed in accordance with **Table 1 - Medical Area - Standard test methods to be used to substantiate claims** for products specified in the '**TS EN 14885, 2022 Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics**' standard (page 20).

Bu ürünlerimiz için “TS EN 14885, 2022 Kimyasal dezenfektanlar ve antiseptikler – Kimyasal dezenfektanlar ve antiseptikler için avrupa standardlarının uygulanması Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics” standardında yer alan Tablo 1 – Medikal Alan - Ürünlerle ilişkin iddiaları doğrulamak için kullanılacak standart test yöntemleri (sayfa 20) gereği, tıbbi cihaz dezenfeksiyonunda kullanılan Kimyasal dezenfektanlar ve antiseptikler için gerekli olan testler tamamlanmıştır.

The microbiological tests on relevant strains have been successfully completed in accordance with the '**TS EN 14885 standard, Table 5 - Medical Area - Test conditions and requirements for standard test methods to be used to substantiate claims for mycobactericidal and tuberculocidal activity of products (Page 35)**' to evaluate the mycobactericidal and tuberculocidal activity of our products.

Ürünlerimizin mikobakterisit ve tüberkülosidal aktivitesini test etmek için “TS EN 14885 standardı, Tablo 5 - Medikal Alan - Ürünlerin mikobakterisit ve tüberkülosidal aktivitesine ilişkin iddiaları doğrulamak için kullanılacak standart test yöntemlerinin test koşulları ve gereksinimleri (Sayfa 35)” doğrultusunda ilgili suşlarda mikrobiyolojik testleri başarı ile tamamlanmıştır.

Our virucidal tests performed in accordance with **EN 14476: 2013 + A2: 2019** standard have the same effect on all enveloped viruses from the same family. As a result, our antiviral tests have been successfully completed and have the same effect on enveloped viruses in the blood such as **HIV, HBV, HCV**.

EN 14476:2013+A2:2019 standardı gereği yapılan virüs testlerimiz aynı aileden ve tüm zarflı virüsler üzerinde aynı etkiye sahiptir. Sonuç olarak Antiviral testlerimiz başarı ile tamamlanmış ve HIV, HBV, HCV gibi kanda bulunan zarflı virüsler için de aynı etkiye sahiptir.

We present this information for your attention.

Bilgilerinize sunarız.

Regards,

Saygılarımızla,

GENERAL MANAGER/ Genel Müdür

GÖKMEN AYDIN

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ANNEX/ EKLER:

- **Annex/Ek 1: TS EN 14885:2022 standard, Table 1 – Medical area- Standard test methods for substantiating product claims**
TS EN 14885 standardı, Tablo 1 – Medikal Alan - Ürünlere ilişkin iddiaları doğrulamak için kullanılacak standart test yöntemleri,
- **Annex / Ek 2: TS EN 14885 standard, 4.3.2.5 Instrument disinfection**
TS EN 14885 standardı, 4.3.2.5 Enstrüman Dezenfeksiyonu
- **Annex / Ek 3: TS EN 14885 standard, 4.3.2.6 Surface Disinfection Without Mechanical Action**
TS EN 14885 standardı, 4.3.2.6 Mekanik Aksiyon olmadan Yüzey Dezenfeksiyonu
- **Annex / Ek 4: TS EN 14885 standard, Table 5 – Medical area – Test conditions and requirements of standard test methods for mycobactericidal and tuberculocidal activity of products**
TS EN 14885 standardı, Tablo 5 - Medikal Alan - Ürünlerin mikobakterisit ve tüberkülosidal aktivitesine ilişkin iddiaları doğrulamak için kullanılacak standart test yöntemlerinin test koşulları ve gereksinimleri
- **Annex / Ek 5: EN 14476:2013+A2:2019 Standardı, Table 1 — Minimum and additional test conditions**
EN 14476:2013+A2:2019 Standardı, Tablo 1 - Minimum ve ek test koşulları

Annex 1:

TS EN 14885:2022 standard, Table 1 – Medical area- Standard test methods for substantiating product claims

TS EN 14885 standardı, Tablo 1 – Medikal Alan - Ürünlerle ilişkin iddiaları doğrulamak için kullanılacak standart test yöntemleri,

Type of activity	Phase, step	Product Claim / Field of Application									
		Hygienic Handrub	Hygienic Handwash	Surgical Handrub or -wash	Surface Disinfection			Instrument Disinfection	Textile Disinfection	Aqueous systems	
					mechanical action without	with	Alf-boorne				
Bactericidal	2,1	EN 13727 (handrub products under clean, handwash products under dirty conditions)			EN 13727			***	EN 13727	**	***
	2,2	EN 1500	EN 1499	EN 12791	EN 17387	EN 16615	EN 17272	EN 14561	EN 16616	***	
Yeasticidal	2,1	EN 13624 (handrub products under clean, handwash products under dirty conditions)			EN 13624			***	EN 13624	*	***
	2,2	***			EN 17387	EN 16615	EN 17272	EN 14562	EN 16616	***	
Fungicidal	2,1	***			EN 13624			***	EN 13624	*	***
	2,2	***			EN 17387	**	EN 17272	EN 14562	EN 16616	***	
Tuberculo-cidal	2,1	EN 14348	EN 14348	***	EN 14348			***	EN 14348	EN 14348 (dirty cond.)	***
	2,2	***			**	**	EN 17272	EN 14563	EN 16616	***	
Mycobactericidal	2,1	EN 14348	EN 14348	***	EN 14348			***	EN 14348	EN 14348 (dirty cond.)	***
	2,2	***			**	**	EN 17272	EN 14563	EN 16616	***	
Virus-cidal against enveloped viruses	2,1	EN 14476	EN 14476	***	EN 14476			***	**	**	***
	2,2	**	**	***	EN 16777	**	***	EN 17111	**	***	
Limited spectrum virus-cidal	2,1	EN 14476	EN 14476	***	EN 14476			***	***	**	***
	2,2	*	**	***	EN 16777	**	***	***	**	***	
Virus-cidal	2,1	EN 14476	EN 14476	***	EN 14476			***	EN 14476	EN 14476 (dirty cond.)	***
	2,2	*	***	***	EN 16777	**	EN 17272	EN 17111	**	***	
Sporicidal against C. diff.	2,1	***			EN 17126			***	EN 17126	EN 17126	***
	2,2	***			**	**	***	**	***	***	
Sporicidal	2,1	***			EN 17126			***	EN 17126	EN 17126	***
	2,2	***			**	**	EN 17272	**	***	***	
Legionella	2,1	***			***			***	***	***	EN 13623
	2,2	***			***			***	***	***	***

* Work item approved (see Annex F).

** No work item yet approved but relevant standards could become available in the future

*** No intention to develop a test.

* Work item approved (see Annex F).

** No work item yet approved but relevant standards could become available in the future

*** No intention to develop a test.

Annex 2:**TS EN 14885 standard, 4.3.2.5 Instrument disinfection*****TS EN 14885 standardı, 4.3.2.5 Enstrüman Dezenfeksiyonu***

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 14561 (2/2)
Yeasticidal activity	EN 13624 (2/1), EN 14562 (2/2)
Additional European Standards	
Fungicidal activity	EN 13624 (2/1), EN 14562 (2/2)
Tuberculocidal / Mycobactericidal activity	EN 14348 (2/1), EN 14563 (2/2)
Virucidal activity against enveloped viruses / Virucidal activity	EN 14476 (2/1), EN 17111 (2/2)
Sporicidal activity against <i>C. diff.</i> / Sporicidal activity	EN 17126 (2/1)

Annex 3:**TS EN 14885 standard, 4.3.2.6 Surface Disinfection Without Mechanical Action***TS EN 14885 standardı, 4.3.2.6 Mekanik Aksiyon olmadan Yüzey Dezenfeksiyonu*

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1)
Yeasticidal activity	EN 13624 (2/1)
Bactericidal / Yeasticidal	EN 17387 (2/2)
Additional European Standards	
Fungicidal activity	EN 13624 (2/1), EN 17387 (2/2)
Tuberculocidal/Mycobactericidal activity	EN 14348 (2/1)
Virucidal activity against enveloped viruses / Limited spectrum virucidal activity / Virucidal activity	EN 14476 (2/1), EN 16777 (2/2)
Sporicidal activity against <i>C. diff.</i> / Sporicidal activity	EN 17126 (2/1)

Annex 4:

TS EN 14885 standard, Table 5 – Medical area – Test conditions and requirements of standard test methods for mycobactericidal and tuberculocidal activity of products
TS EN 14885 standardı, Tablo 5 - Medikal Alan - Ürünlerin mikobakterisit ve tüberkülosidal aktivitesine ilişkin iddiaları doğrulamak için kullanılacak standart test yöntemlerinin test koşulları ve gereksinimleri

EN reference Phase, step	Test organisms	Temperature °C	Contact time	Interfering substances	Logarithmic reduction expressed in lg
EN 14348 2.1	Obligatory test conditions				
	<u>tuberculocidal activity:</u> only <i>Mycobacterium terrae</i> ATCC 15755 or <u>mycobactericidal activity:</u> <i>Mycobacterium avium</i> ATCC 15769 and <i>Mycobacterium terrae</i> ATCC 15755	20	60 min	<u>Clean conditions:</u> bovine albumin 0,3 g/l and/or <u>Dirty conditions:</u> bovine albumin 3,0 g/l plus sheep erythrocytes 3 ml/l	≥ 4,0
	The following additional test conditions are permitted:				
		10 °C-steps	5 min, 15 min, 30 min		≥ 4,0
Remark EN 14348 may be used to demonstrate mycobactericidal and/or tuberculocidal activity for hygienic handrub (4.3.2.2) and – wash (4.3.2.3) products, surface disinfectants (4.3.2.6 and 4.3.2.7) and chemical disinfectants for textile (4.3.2.8). In these cases the contact times shall be adapted according to the principles described in EN 13727 and EN 13624.					

Annex 5:

EN 14476:2013+A2:2019 Standardı, Table 1 — Minimum and additional test conditions
*EN 14476:2013+A2:2019 Standardı, Tablo 1 - Minimum ve ek test koşulları***Table 1 — Minimum and additional test conditions**

Test Conditions	Hygienic handrub and handwash	Instrument disinfection	Surface disinfection	Textile disinfection
Minimum spectrum of test organisms	A₂ Virucidal activity Poliovirus Adenovirus Murine Norovirus Limited spectrum virucidal activity ^a Adenovirus Murine Norovirus A₁ Virucidal activity against enveloped viruses ^b Vacciniavirus A₁	A₂ Virucidal activity Poliovirus Adenovirus Murine Norovirus when temperature is 40 °C or higher: only Parvovirus	A₂ Virucidal activity Poliovirus Adenovirus Murine Norovirus A₂ Limited spectrum virucidal activity ^a adenovirus murine norovirus Virucidal activity against enveloped viruses ^b vaccinia virus A₂	Parvovirus
additional	Any relevant test organism			

^a **A₂** The test for "limited spectrum virucidal activity" will cover all enveloped viruses (Annex A) and norovirus, rotavirus and adenovirus. **A₂**

^b **A₁** The test for **A₂** "virucidal activity against enveloped viruses" **A₁** will cover all enveloped viruses only (Annex A). **A₁**

^c The contact times for surface disinfectants stated in this table are chosen on the basis of the practical conditions of the product. The recommended contact time for the use of the product is within the responsibility of the manufacturer. Products intended to disinfect surfaces that are likely to come into contact with the patient and / or the medical staff and surfaces, which are frequently touched by different people, leading to the transmission of microorganisms to the patient, shall be tested with a contact time of maximum 5 min. The same applies where the contact time of the product shall be limited for practical reasons. Products for other surfaces than stated above may be tested with a contact time of maximum 60 min.

^d Hygienic handrub shall be tested as a minimum under clean conditions.

^e Hygienic handwash shall be tested as a minimum under dirty conditions.

^f For the additional conditions, the concentration defined as a result can be lower than the one obtained under the minimum test conditions.