HYGIENE NORD GMBH
C/O BIOTECHNIKUM
WALTHER-RATHENAU-STRASSE 49 A
17489 GREIFSWALD
DEUTSCHLAND - GERMANY

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HYGIENE NORD GMBH

HYGIENE NORD GMBH, C/O BIOTECHNIKUM, W.-RATHENAU-STR. 49 A, D-17489 GREIFSWALD

Liquid-Universum GmbH

Grunbacher Str. 59 - 65

71384 Weinstadt

Deutschland / Germany

CUSTOMER NUMBER	DATE
1871	November 26, 2020

REPORT 202395.VI

VIRAZER SOFT

YEASTICIDAL ACTIVITY

- EN 1650 -

Purpose

The yeasticidal activity of the product formulation **VIRAZER SOFT** (Liquid-Universum GmbH, Weinstadt, Germany) should be evaluated in accordance with the European Standard **EN 1650 (2019)**.

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Test description

Order number:	A 20-0575
Manufacturer:	Liquid-Universum GmbH, Weinstadt, Germany
Product:	**VIRAZER SOFT**
Batch number:	LU20200427
Manufacture date:	04 / 2020
Best before:	not provided
Sample number:	P 205662
Date of order:	September 11, 2020
Date of delivery:	September 14, 2020
Test date:	November 04, 2020 – November 06, 2020
Basis:	EN 1650 (2019) Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – test method and requirements (phase 2, step 1)
Test organism:	*Candida albicans* ATCC 10231
Test solutions:	80 %, 50 % and 10 %
Active ingredients in 100 g [1]:	79.25 g ethanol
Odour:	alcoholic
Appearance:	clear, colourless liquid
Appearance of dilution:	clear, colourless liquid
pH – value (pH-Meter):	100 %: 5.11 50 %: 4.94 10 %: 4.86 WFI: 5.77
pH – value (pH-stripes):	100 %: 5
Neutralizer:	4 % Tween 80 + 3 % Saponin + 0.4 % Lecithin + 0.25 % SDS (Neutralizer XXIV)
Interfering substances:	0.3 % albumin (dirty conditions)
Contact time:	30 s
Test temperature:	20 ± 1 °C
Incubation temperature:	30 ± 1 °C

Test Method

Quantitative suspension test

Testing is based on the European Standard EN 1650 (2019). Validation and control procedures are therefore carried out in accordance with that standard.

For the test, to a sample of the product **VIRAZER SOFT** (diluted with water for injections, if necessary) 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 times. At the end of the contact time, an aliquot of 1 ml is taken; the microbiocidal activity in this portion is immediately neutralized. Two 1 ml samples (if applicable: per dilution step) of this suspension are spread on at least 2 plates each or on 1 plate each using the pour-plate-technique. 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.

The test is performed under dirty conditions of 0.3 % albumin using *C. albicans* as test organism. Results are presented in tables 1.

Results [2]

In accordance with the EN 1650 (2019), the batch LU20200427 of the test product **VIRAZER SOFT**, when applied at a product concentration of at least **50 %**, **possesses** yeasticidal efficacy (log_{10} RF ≥ 4) at 20 ± 1 °C in **30 s** under **dirty conditions** for reference strain *C. albicans* (tables 1).

Results are validated in accordance with the requirements of the EN 1650 (2019).

Greifswald, November 26, 2020

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- General Manager -

Axel Kramer

Prof. Dr. med. A. Kramer
- MD for Hygiene and Environmental Medicine -

Table 1: Results of the quantitative suspension test according to EN 1650 (2019)

Date:	November 06, 2020	**Order number:**	A 20-1134
Product:	**VIRAZER SOFT**	**Sample number:**	P 205662
Test organism:	*C. albicans*	**Batch number:**	LU20200427
Interfering substance:	0.3 % albumin		
Incubation temperature:	30 ± 1 °C	**Neutralizer:**	XXIV
Test suspension (N_0):	$4.00*10^6$ cfu/ml (6.60 log)	**Incubation time:**	48 h
Validation Suspension (N_V):	$1.39*10^3$ cfu/ml (3.14 log)	**Test temperature**	20 ± 1 °C

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	**> 4.46**
50 %	1 ml (10^0)	3	17	12	13	20	25	2.35	**4.25**
10 %	1 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660	> 3.82	**< 2.78**

Validation and Controls

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}	67	73	140	**139.5**	V_{c1}	59	64	123	**123**	V_{c1}	75	75	150	**146**	V_{c1}	60	51	111	**115**
V_{c2}	70	69	139		V_{c2}	60	63	123		V_{c2}	70	72	142		V_{c2}	60	59	119	
$30 \leq \bar{x}$ of $N_{VO} \leq 160$?					$\bar{x}$ of A is $\geq 0.5 * \bar{x}$ of N_{VO}?					$\bar{x}$ of B is $\geq 0.5 * \bar{x}$ of N_{VO}?					$\bar{x}$ of C is $\geq 0.5 * \bar{x}$ 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.
MW	=	average value
x	=	average value
$\bar{x}$	=	average value
RF	=	reduction factor
> 330	=	not countable
> 660	=	not countable
n.d.	=	not determined
WFI	=	water for injections