Laboratoire MIDAC
Your expert in microbiology

cofrac ESSAIS
Accréditation n°1-0019
Portée disponible sur www.cofrac.fr

Evaluation of the virucidal activity according to the NF EN 14476 + A2 : 2019 standard
Product : SQ2 Skin
Batch: /

On request of:

MEDIMEX
1 allée Alban Vistel
FR69110 Sainte-Foy-les-Lyon

Loos, the 31 December 2020

Isabelle WATBLED
Test Manager

The test report includes : **9** pages

The COFRAC accreditation attests laboratories are competent for the only tests covered by the program.
Copy of this test report is authorized only in its entirety.
This report concerns only the tested product.

1 PRINCIPLE

The virucidal activity was determined according to the protocol of the NF EN 14476+A2 standard: "Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (phase 2, step 1)." - July 2019.

2 IDENTIFICATION OF SAMPLE

Product : **SQ2 Skin**
Batch number and expiration date : ***/*, - 15 October 2022**
Customer : **MEDIMEX**
Date of delivery : **15 October 2020**
Storage conditions : **Room temperature.**
Recommended product diluent : **Distilled water.**
Active substances and concentration : **Alkyldimethylbenzyammonium Chloride (0.32%)**
Product appearance : **colorless liquid.**

3 EXPERIMENTAL CONDITIONS

Period of analysis : **18 December 2020** to **31 December 2020**
Product diluents used : **Distilled water.**
Product test concentrations : **see table(s) on next page(s).**
Appearance product dilutions : **transparent, clear, homogeneous.**
Test temperature : **20°C (± 1°C).**
Contact times : **60sec±5 sec**
Interfering substances : **0.3 g/l bovine albumin (Clean conditions)**
Stability of mixture: **None precipitate observed during the test**
Incubation temperature : **37°C (± 1°C)**
Filtration method : **microfiltration**
Columns: Microspin S-400 HR columns
Identification of virus : **Vaccinia virus Elstree strain *p1***
Method used for product inactivation : **Microspin S-400 HR columns, according to the manufacturer's protocol**
Identification of cells : **Vero cells, CCL-81, p6, MEM 10%SVF, 1% AANE, 1%ATB, 1%L-Glu**

4 TEST METHOD AND RESULTS

1) Method

1-part interfering substance + 1-part virus suspension + 8-parts biocide were mixed and incubates at the indicated contact temperature for the indicated contact times. Assays were validated by a cytotoxicity control, interference control, neutralization control and a formaldehyde internal standard. The calculation of titer reductions is based on the method of Spearman and Kärber and is measured as the difference between the titer of the virus control and the titer of product test solution.

2) Results

Virus suspension: **8.00E+00** log $DITC_{50}$
Maximum detectable virus inactivation: **5.50E+00** log $DITC_{50}$
Inactivation of the test virus inactivation reference after 15 min: **3.13E+00** log $DITC_{50}$

4 TEST METHOD AND RESULTS

1) Method

1-part interfering substance + 1-part virus suspension + 8-parts biocide were mixed and incubates at the indicated contact temperature for the indicated contact times. Assays were validated by a cytotoxicity control, interference control, neutralization control and a formaldehyde internal standard. The calculation of titer reductions is based on the method of Spearman and Kärber and is measured as the difference between the titer of the virus control and the titer of product test solution.

2) Results

Virus suspension: **8.00E+00** log $DITC_{50}$
Maximum detectable virus inactivation: **5.50E+00** log $DITC_{50}$
Inactivation of the test virus inactivation reference after 15 min: **3.13E+00** log $DITC_{50}$

5 EXPERIMENTAL RESULTS

e) Virucidal studies

Product	Test concentration	Interfering substance	Viral titer in the test (log $_{DICT50}$)	Reduction (log $_{DICT50}$)
SQ2 Skin: /	**1%(v/v)**	**0.3 g/l bovine albumin (Clean conditions).**	**4.00E+00**	**4.00E+00**
	50%(v/v)		**2.50E+00**	**5.50E+00**
	80%(v/v)		**2.50E+00**	**5.50E+00**
Viral control T0			**7.63E+00**	
Viral control Tmax			**8.00E+00**	

Comment: *At least one concentration per test must show a reduction of 4log or more, and at least one concentration must show a log reduction of less than 4*

Dans le cadre de la norme, le SQ2SKIN a été testé à différentes concentrations (1%, 50% et 80%) dilué dans de l'eau distillé.
Afin que l'efficacité virucide (virus de la vaccine) soit validée, le log DICT50 (montrant la réduction de virus) doit être strictement supérieur à 4.
Pour le SQ2SKIN, le log DICT50 est strictement supérieur à 4 pour une concentration de 50% et 80%.

Cela signifie donc que le SQ2SKIN possède une activité virucide.

6 METHODOLOGY VERIFICATION

A test is only valid if the following criteria are fulfilled:

a/ Test virus suspension has at least a concentration which allows the determination of a 4 log10 reduction of the virus titer.

b/ The difference between the titer of the viral control, expressed as a logarithm, and the titer of the virus in the inactivation reference test is

between -0,5 and -2,5 after 30min and between -2 and -4,5 after 60min for poliovirus,

between -3 and -5 after 30min and -3,5 and 5,5 after 60min for adenovirus,

between 0.0 and -2 after 30min and -0.5 and 2,5 after 60min for parvovirus,

between -0.75 and -3,5 after 5min and between -2,0 and ≥ -4 after 15min for vaccina virus,

between -1 and -3 after 30min and between -2,0 and -4,0 after 60min for murine norovirus

c/ Cytotoxicity of the product does not affect cell morphology and growth or susceptibility for the test virus in the dilutions of the test mixtures which are necessary to demonstrate a 4log reduction of the virus.

d/ Comparative titration of the virus on the treated cell cultures with dilutions of the test mixture and in parallel with PBS results in a difference <1 lg of the viral titer.

e/ When checking the efficiency of the neutralization of product activity, the difference of titer with the test suspension must be ≤ 0.5log

f/ At least one concentration per test must show a reduction of 4log or more, and at least one concentration must show a log reduction of less than 4

7 CONCLUSION

According to **NF EN 14476+A2 : 2019 standard**, The product

SQ2 Skin
lot : /

possesses a virucidal activity tested at **50%** after **60sec +/- 5sec** at **20°C (± 1°C)** with **0.3 g/l bovine albumin (Clean conditions)** against: Vaccinia virus Elstree strain