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Eurovir® Hygiene-Labor
Antivirale Validierung & Rabies

Testing the virucidal activity of the product *Shieldex® Kiel-SK-96*

Screening test using a praxis-near carrier test system following ISO 21702:2019 against the *Bovine Coronavirus (BoCV-Coronavirus)* - Test run S2 dated 12.06.2020

Short report: screening test S2

by
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Test period: in June 2020

Principal: STATEX Produktions- und Vertriebs GmbH
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Products:

- Test item w/o the active component: Shieldex® PBN II Raw material 1,5 Oz
- Test item with active component: Shieldex® Kiel-SK-96
- All test items were applied by the principal

Test parameter:

- Test conditions: T = 25 °C (according to ISO 18184) and 90 % r.LF
- Protein load: no additional protein load; the virus material (cell culture supernatant) was spread onto the surface(s) w/o any further manipulation/alteration
- Volume to square ratio: 157 µL distributed to 3,14/cm² (discs, with d = 2 cm)
- Incubation: 7 min., 15 min. and 30 min. in a climate chamber (KBF 115; Fa. Binder).
- The test discs were placed into the wells of a 12-well cell culture plate (TPP). Incubation was carried out with the lid closed.
- Recovery of the virus material was performed in the same wells as the incubation. After 5 mL of cell culture medium had been added to the well, the sample disk was rinsed repeatedly (15x) with V = 1 mL of medium using a pipette.

Test system:

- Bovines Coronavirus (Beta-Coronavirus); Stamm: S379 Riems
  (Origin: Virusbank of the Friedrich Löffler-Institute, Insel Riems, Germany)
- HRT-18 cells
  (Origin: Inst. f. Hygiene und Infektionskrankheiten der Tiere, Giessen, Germany)

Test procedure:

- The test was performed following ISO 18184:2019. Test principle: quantitative virucidal carrier test at T = 25 °C (in a climate chamber)
- the test was performed w/o (additional) protein load

***Tab. 1:* Product samples tested**

No.	Product (s)	Storage conditions [1]
#1	Shieldex® PBN II Raw material 1,5 Oz (control sample)	at RT
#2	Shieldex® Kiel-SK-96 (test sample)	at RT

[1] = *access limited*

Performing the test

Coating of the test items

- The textile test material (active and control samples) were equipped with the antiviral coponent by the client, who provided this material as ready-to-use material.
- At Eurovir, round sample disks (test disks) with d = 2 cm were cut out of this sample material using a hole punch.

Performing the test

- From the square shaped product material round test disks were prepared using a 2 cm hole punch. Afterwards, the disks were transferred to a 12-well cell culture plate where the testing was then carried out. The incubation was performed with the lid closed.
- The test samples were not sterilised by autoclaving. The test material consists of a synthetic fiber, which does not survive the autoclaving.

Test results:

Observations:

- With the "Virus control" sample disks (VK; sample material without equipment), not all of the virus suspension was absorbed by the textile specimen. Consequently, the test disk was partially immersed in the virus suspension.
- When the test disks (coated with product) were inoculated, the virus material initially remained as small droplets on the surface. As the time progressed, the material was absorbed completely.
- The test disks (coated with product) were provided with a self-adhesive material on the back (including a protective film). As a consequence, these test disks were liquid-tight towards the bottom - in contrast to the control material (VK).
- Up to 30 min. of incubation no drying of the material was observed.
- Resuspending of the virus material was performed apparently unremarkable.
- No further observations / unforeseen events were recorded

Virustitrations

Tab. 2.1: Virus control *(Virus titration by limiting dilution)*

Sample	VK-1a	VK-1b
	Virus control / 1 h	
Titer/Test vol. ($lg\ ID_{50}$)	5,1	5,1
av. virus titer ± K (95%) [1]	**5,10 ± 0,29 / 100 µL**	

[1] = Calculation of the virus titer and its 95% confidence interval according to EN14476

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***Tab. 2.2*: Virus inactivation** (Virus titration by limiting dilution)*

Sample	In-7a	In-7b	In-8a	In-8b	In-9a	In-9b
	Shieldex® Kiel-SK-96 / 7 Min.		Shieldex® Kiel-SK-96 / 15 Min.		Shieldex® Kiel-SK-96 / 30 Min.	
Titer/Test vol. (lg ID_{50})	≤ 0,30	≤ 0,30	≤ 0,30	≤ 0,30	≤ 0,30	≤ 0,30
av. virus titer ± K (95%) [1]	≤ 0,30		≤ 0,30		≤ 0,30	
Reduction [2] (lg ID_{50} ± K [95%])	**≥ 4,80 ± 0,29**		**≥ 4,80 ± 0,29**		**≥ 4,80 ± 0,29**	

[1] = Calculation of the virus titer and its 95% confidence interval according to EN14476
[2] = Virus reduction: lg ID_{50} of virus input (virus control) minus lg ID_{50} of sample (at the given time point)

***Virus inactivation:** (cf. Tab. 2)*

- Shorter contact times were tested as part of this test (t = 7, 15 and 30 minutes). The virus control VK-1 was used as a reference point for determining the virus reduction.
- Even after the shortest contact time (t = 7 min.) no residual virus was detectable in both test samples. With the two longer contact times the same result was obtained (no residual test virus detectable). Accordingly the product-associated reduction factor was determined to RF ≥ 4,80 ± 0,29 with all three contact times.

Conclusions:

- Even with the shortest contact time a significant virus reduction was recorded. With no residual test virus detected virus reduction amounted to RF ≥ 4,8 (corresponding to a reduction rate of more than 99,99%).
- It can be concluded from the data obtained that under the test conditions a high-level virus-inactivating effect against the *bovine coronavirus* was given. This high-level virus-inactivating effect can be attributed to the antimicrobial equipment.
- The observed virus-inactivating effect of the coating was determined using the *bovine coronavirus* as the test virus. This virus belongs to the enveloped viruses which are in general considered to be inactivated comparable easily. This means that the observed virus inactivation cannot be transferred necessarily to other viruses. This may also apply to other enveloped viruses.

Annotation:

- The data described above were collected in a so-called screening test. This test is a basic test, carried out based on the underlying set of rules and with the omission of validity checks. This test therefore does not correspond to a complete product validation according to ISO 18184.

Luckenwalde, 10th of June 2020

Dr. Ch. Jursch
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