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Bremen, 07/07/2015

Summary: virus-inactivating properties of Biofilm Stop Cleaner of Fakolith Chemical Systems SLU according to EN 14476:2013/FprA1 March 2015

This summary is based on the following test reports of Dr. Brill + Partner GmbH for the surface disinfectant Biofilm Stop Cleaner produced by Fakolith Chemical Systems SLU:

poliovirus test report 28/05/2015 adenovirus test report 17/06/2015 MNV test report 05/06/2015

The following concentration and exposure time are necessary for the inactivation of the three test viruses:

5.0 % 15 minutes

in order to achieve a four \log_{10} reduction (inactivation ≥ 99.99 %) under clean conditions in a quantitative suspension test according to EN 14476:2013/FprA1 March 2015.

After evaluation with poliovirus type 1, adenovirus type 5 and MNV the surface disinfectant Biofilm Stop Cleaner can be declared as having "virucidal" properties according to EN 14476:2013/FprA1 March 2015.

This declaration is explained in the EN 14476:2013 as follows:

1 Scope

This European Standard specifies a test method and the minimum requirements for virucidal activity of chemical disinfectant and antiseptic products that form a homogeneous physically stable preparation when diluted with hard water – or in the case of ready-to-use products, i. e, products that are not diluted when applied,— with water. Products can only be tested at a concentration of 80 % (97 %, with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substance.

This European Standard applies to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, instrument disinfection by immersion, surface disinfection by wiping, spraying, flooding or other means and textile disinfection.

This European Standard applies to areas and situations where disinfection is medically indicated. Such indications occur in patient care, for example:

- in hospitals, in community medical facilities, and in dental institutions:
- in clinics of schools, of kindergartens, and of nursing homes;

and may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for the patients.

NOTE 1 The method described is intended to determine the activity of commercial formulations or active substances under the conditions in which they are used.

NOTE 2 This method corresponds to a phase 2, step 1 test

NOTE 3 EN 14885 specifies in detail the relationship of the various tests to one another and to "use recommendations".

Dr. Jochen Steinmann

From Annex B in EN 14476 Examples of viruses which may contaminate human medical instruments, hands, surfaces (Enveloped viruses are in bold)

NOTE

This list is not exhaustive.

Blood

Enterovirus Filoviridae Flavivirus Herpesviridae

Hepatitis A Virus (HAV) **Hepatitis B virus (HBV)**

Respiratory tract

Adenovirus (Mast-) **Coronavirus** Enterovirus **Herpesviridae**

Neural tissue, ear & nose, eye

Adenovirus (Mast-) Enterovirus

Herpesviridae Measles Virus

Gastro-intestinal

Adenovirus (Mast-) Caliciviridae

Coronavirus Astrovirus

Skin, breast and/or milk

Enterovirus **Herpesviridae**

Human Immunodeficiency Virus (HIV)

Spleen and lymph nodes (see also "Blood")

Human T Cell Leukemia Virus (HTLV) Human Immunodeficiency Virus (HIV)

Dental procedure

Adenovirus (Mast-) Enterovirus **Herpesviridae**

Hepatitis B virus (HBV)

Hepatitis C virus (HCV) Hepatitis Delta virus (HDV)

Human Immunodeficiency Virus (HIV) Human T Cell Leukemia Virus (HTLV)

Parvovirus B 19

Influenza Virus Paramyxoviridae

Rhinovirus **Rubella Virus**

Human Immunodeficiency Virus (HIV)

Polyomavirus Rabies Virus Rubella Virus

Enterovirus

Hepatitis A Virus (HAV) Hepatitis E Virus (HEV)

Rotavirus

Human T Cell Leukemia Virus (HTLV)

Papillomavirus **Poxviridae**

Hepatitis C Virus (HCV)
Hepatitis Delta Virus (HDV)

Human Immunodeficiency Virus (HIV)

Urogenital tract

Hepatitis B Virus (HBV) Herpesviridae Human Immunodeficiency Virus (HIV) **Human T Cell Leukemia Virus (HTLV)** Papillomavirus Polyomavirus

Reference:

Van Regenmortel MHV et al., Eds.: Virus Taxonomy, Classification and Nomenclature of Viruses, seventh report of the international committee on taxonomy of viruses.

Academic Press, San Diego, 2000