



Public Health Institute Ostrava
Center of clinical laboratories
Testing laboratory n. 1554 accredited according to
ISO/IEC 17025
Partyzánské nám.7, 702 00 Ostrava
VAT: CZ71009396
Laboratory for testing virucidal effect



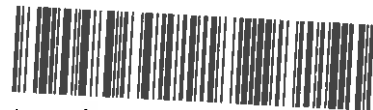
TEST REPORT n. 5/2013/SVU

Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2/ step 1) according EN 14476 + A1: 2007

Zdravotní ústav se sídlem v
Doručeno: 24. 03. 2014
ZU/06904/2014
listy: 23 přílohy:

Customer:

BOCHEMIE a.s.
Lidická 326
735 95 Bohumín
CZ



zuso0es566d78c9

Order number: 00021479

Reference number: 5/2013/SVU

Identification of disinfectant – sample:

Product name:	CHLORAMIX DT
Lot number:	001A131106
Expiration:	8/2015
Producer:	Bochemie a.s.
Storage conditions:	-20 až +30°C
Diluent product recommended by the producer for use:	water
Product appearance:	solid, tablets, weight of one tablet 3,3 – 3,5 g
The active substance (s) and its (their) concentration:	Sodium dichloroisocyanurate, dihydrate, active chlorine content min.43% = 1.5 g active Cl ₂ /tablet
Purpose of product:	Instrument and surface disinfection
Date of delivery of the product:	3.12.2013
Date of test:	7.1.2014 – 5.2.2014

Without written consent of the testing laboratory, the protocol shall not be reproduced except in full. The result of test relate only to the tested sample. The center of clinical laboratories - testing laboratory n. 1554 accredited according to ISO/ IEC 17025. List of accredited methods is show in www.zu.cz. The sample was examined by SOP No.1901

Results - for details see annex

According the EN 14476+A1 the test product CHLORAMIX DT, designed for surface and instrument disinfection, working solution 1 tablet in 1,5 l water, demonstrate virucidal activity after an exposure time 15 min, 30 min and 60 min, at temperature 20°C±1°C, under dirty conditions (3,0 g/l bovine serum albumin plus 3,0 ml erythrocytes), using viral titration on monolayer cell culture on a microtitre plate by reduction of reference virus *Adenovirus type 5, strain Adenoid 75* by more than 4 lg.

According the EN 14476+A1 the test product CHLORAMIX DT, designed for surface and instrument disinfection, working solution 1 tablet in 7 l water, does not demonstrate virucidal activity after an exposure time 15 min, 30 min and 60 min, at temperature 20°C±1°C, under dirty conditions (3,0 g/l bovine serum albumin plus 3,0 ml erythrocytes), using viral titration on monolayer cell culture on a microtitre plate by reduction of reference virus *Adenovirus type 5, strain Adenoid 75* by more than 4 lg.

According the EN 14476+A1 the test product CHLORAMIX DT, designed for surface and instrument disinfection, working solution 1 tablet in 10 l water, does not demonstrate virucidal activity after an exposure time 15 min, 30 min and 60 min, at temperature 20°C±1°C, under dirty conditions (3,0 g/l bovine serum albumin plus 3,0 ml erythrocytes), using viral titration on monolayer cell culture on a microtitre plate by reduction of reference virus *Adenovirus type 5, strain Adenoid 75* by more than 4 lg.

Conclusion:

Working solution of test product CHLORAMIX DT prepared dissolving 1 tablet in 1,5 l water demonstrate according EN 14476+A1 virucidal activity under the dirty conditions after exposure time 15 min.

Working solution of test product CHLORAMIX DT prepared dissolving 1 tablet in 7 l water does not demonstrate according EN 14476+A1 virucidal activity under the dirty conditions.

Working solution of test product CHLORAMIX DT prepared dissolving 1 tablet in 10 l water does not demonstrate according EN 14476+A1 virucidal activity under the dirty conditions.

In Ostrava, 6.2.2014

Zdravotní ústav se sídlem v Ostravě
Partyzní nám. 7. 726/02 Ostrava
15. 7. 2014
Porubová

Mgr. Ludmila Porubová
Guarantor of testing

Annex to the protocol n.: 5/2013/SVU

Product name: CHLORAMIX DT
Lot number: 001A131106
Expiration: 11/2018
Producer: Bochemie a.s.

Date of delivery of product 3.12.2013
Date of test: 7.1.2014 – 5.2.2014

Experimental conditions: Quantitative suspension test for the determine of virucidal effect of disinfectant according the EN 14476 + A1 (SOP n. 1901)

Time of testing: 7.1. – 5.2.2014
Testing temperature: 20°C±1°C
Titration method: viral titration on monolayer cell culture on the microplate
Testing concentration: 1 tablet/1,5 l water, 1 tablet/7 l water, 1 tablet/10 l water
Contact time: 15 min, 30 min, 60 min
Test conditions: dirty conditions – 3,0 g/l bovine serum albumin (BSA) plus 3,0 ml erythrocytes
Proces of stopping the effect of product: virucidal activity of product is suppressed by transferring the sample into the ice cold diluent

Reference substance: Sodium hypochlorite
Used virus: *Adenovirus type 5, strain Adenoid 75* (ATCC)
Cell line: HeLa cells (ATCC)
Titers calculated by: Spaerman – Kärber's method

Test detail:

1. Preparation of tissue culture testing
2. Preparation of the test virus suspension
3. Test infectivity of the virus
4. Titration of the virus with the conditions
5. The cytotoxic effect of the product
6. Reference viral inactivation test
7. Viral inactivation test of product
8. Control of susceptibility

Table n.1 The results of the test for product CHLORAMIX DT to *Adenovirus type 5, strain Adenoid 75*

Product	Concentration	Interfering substance	Level of cytotoxicity	$-\log_{10}ID_{50}$ after 15 min	$-\log_{10}ID_{50}$ after 30 min	$-\log_{10}ID_{50}$ after 60min
CHLORAMIX DT	1 tbl/ 1,5 l vody	3,0 g/l BSA + erythrocytes	1,5	2,1	1,5	1,9
CHLORAMIX DT	1 tbl/ 7 l vody	3,0 g/l BSA + erythrocytes	1,5	6,7	6,1	5,5
CHLORAMIX DT	1 tbl/ 10 l vody	3,0 g/l BSA + erythrocytes	1,5	6,5	6,5	5,5
Sodium hypochlorite	0,5 % (w/v)	Hard water	2,5	-	-	2,5
Virus control	-	3,0 g/l BSA + erythrocytes	-	7,5	-	7,3

Table n.2 The effect of product CHLORAMIX DT 1 tbl/ 1,5 l water to *Adenovirus type 5, strain Adenoid 75*

Concentration	Virus suspension titre - $\log_{10}ID_{50}$	Interfering substance	Contact time	Test titre - $\log_{10}ID_{50}$	$\Delta\log_{10}ID_{50}$
1 tbl/ 1,5 l water	7,5	3,0 g/l BSA + erythrocytes	15 min	2,1	5,4
1 tbl/ 1,5 l water	7,5	3,0 g/l BSA + erythrocytes	30 min	1,5	6,0
1 tbl/ 1,5 l water	7,3	3,0 g/l BSA + erythrocytes	60 min	1,9	5,4

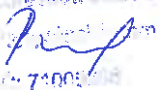
Table n.3 The effect of product CHLORAMIX DT 1 tbl/ 7 l water to *Adenovirus type 5, strain Adenoid 75*

Concentration	Virus suspension titre - $\log_{10}ID_{50}$	Interfering substance	Contact time	Test titre - $\log_{10}ID_{50}$	$\Delta\log_{10}ID_{50}$
1 tbl/ 7 l water	7,5	3,0 g/l BSA + erythrocytes	15 min	6,5	1,0
1 tbl/ 7 l water	7,5	3,0 g/l BSA + erythrocytes	30 min	6,1	1,4
1 tbl/ 7 l water	7,3	3,0 g/l BSA + erythrocytes	60 min	5,5	1,8

Table n.4 The effect of product CHLORAMIX DT 1 tbl/ 10 l water to *Adenovirus type 5, strain Adenoid 75*

Concentration	Virus suspension titre - $\log_{10}ID_{50}$	Interfering substance	Contact time	Test titre - $\log_{10}ID_{50}$	$\Delta\log_{10}ID_{50}$
1 tbl/ 10 l water	7,5	3,0 g/l BSA + erythrocytes	15 min	6,5	1,0
1 tbl/ 10 l water	7,5	3,0 g/l BSA + erythrocytes	30 min	6,5	1,0
1 tbl/ 10 l water	7,3	3,0 g/l BSA + erythrocytes	60 min	5,5	1,8

Prepared by: Mgr. Ludmila Porubová

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