個別診断／試験結果／効能証明書

デュールデンタル ハイジーンシステム

FD350 surface disinfection
除菌ワイプ｜表面の除菌

2019年2月現在

DÜRR DENTAL

個別診断／試験結果／効能証明書
FD350 surface disinfection
除菌ワイプ｜表面の除菌

FD350の菌及び真菌への機械的／非機械的作業下での表面除菌効果検証

PD Dr. med. H.-P. Werner 2008/10/29

Surface Disinfection with and without mechanical action Bactericidal and fungicidal (C. albicans) efficacy Clean conditions

ドイツ応用衛生協会（DGHM）基準に従い、衛生環境下における定量的浮遊実験と診療を想定した実使用試験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌、C.アルビカンスに対して行った結果、FD350（100%濃度/未希釈）は機械的作業で15秒、非機械的作業で30秒の作用時間で十分な有効性を示し、以上の試験結果はDGHMの消毒リストの評価基準を満たしていることが実証された。

PROF. DR. MED. H. - P. WERNER
FACHARZT FÜR HYGIENE

c/o HygCen Centrum für Hygiene und
medizinische Produktsicherheit GmbH
Bornhövedstraße 78
D-19055 Schwerin
Tel.: +49 (0)385 / 56 82 65
Fax: +49 (0)385 / 56 82 67
E-Mail: hpwerner@hygcen.de

Prof. Dr. H.-P. Werner · c/o HygCen GmbH · Bornhövedstr. 78 · D-19055 Schwerin

orochemie GmbH + Co KG

Max-Planck-Straße 27

D-70806 Kornwestheim

2008-10-29

DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher
Surface Disinfection with and without mechanical action
Bactericidal and fungicidal (C. albicans) efficacy
Clean conditions

EXPERTISE

After testing the **disinfectant DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher** in accordance with the

„Standard Methods of the DGHM for testing of chemical disinfection processes" (Status: 2001-09-01)

I hereby issue the following evaluation of the results from the test report 2008-10-29 (SN 8047):

Results of the in vitro-tests

On the basis of the results of the qualitative suspension tests, the results obtained with the 4 test strains in the following quantitative suspension tests were evaluable.

The quantitative suspension tests were carried out under **clean conditions** in spread plate technique for germ detection.

DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher resulted in sufficient reductions (5 lg. units of the test bacteria or 4 lg. units of C. albicans)

under **clean conditions**

in 75 % within 15 secounds

Results under practical conditions

The efficacy of the disinfectant **DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher** was tested with and without mechanical action **under clean condition** against the 4 test strains.

In the test **with mechanical action** resulted under this condions the

concentrate within 15 secounds

in sufficient reductions against the test strains S.aureus, E.hirae, P.aeruginosa and C.albicans.

In the test **without mechanical action** resulted under this conditions the

concentrate within 30 secounds

in sufficient reductions against the test strains S.aureus, E.hirae, P.aeruginosa and C.albicans.

Application recommendations for
DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher
for surface disinfection with and without mechanical action

According to the results obtained, **DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher** complies with the

> „Requirements Specification for the Admission of Chemical Disinfection Processes in the DGHM Disinfectant List" (Status: 2002-02-04)

for surface disinfection **with mechanical action**
under **clean conditions**

in 100 % in 15 secounds

and for surface disinfection **without mechanical action**
under **clean conditions**

in 100 % in 30 secounds.

Prof. Dr. med. H.-P. Werner

FD350の菌及び真菌への機械的作業下での表面除菌効果検証

PD Dr. med. H.-P. Werner 2004/11/06

Surface disinfection without mechanical action Bactericidal and fungicidal (C. albicans) efficacy

DGHMのガイドラインに従い、衛生状況下における定量的浮遊実験と診療を想定した実使用試験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌、C.アルビカンスに対して行った結果、FD350（100%濃度/未希釈）は非機械的作業で1分の作用時間でDGHMの消毒リストの化学的消毒剤の評価基準を満たしていることが実証された。

PROF. DR. MED. H. - P. WERNER
FACHARZT FÜR HYGIENE

c/o HygCen Centrum für Hygiene und
medizinische Produktsicherheit GmbH
Bornhövedstraße 78
D-19055 Schwerin
Tel.: +49 (0)385 / 56 82 65
Fax: +49 (0)385 / 56 82 67
E-Mail: hpwerner@hygcen.de

Prof. Dr. H.-P. Werner · c/o HygCen GmbH · Bornhövedstr. 78 · D-19055 Schwerin

Orochemie
DÜRR + PFLUG GmbH + Co KG
Max-Planck-Straße 27

D- 70806 Kornwestheim

2004-11-06

DÜRR SYSTEM-HYGIENE FD 350 DESINFEKTIONSTÜCHER (WIRKSTOFFLÖSUNG)
Surface disinfection without mechanical action
Bactericidal and fungicidal (C. albicans) efficacy

EXPERTISE

After testing the disinfectant **DÜRR SYSTEM-HYGIENE FD 350 DESINFEKTIONSTÜCHER (WIRKSTOFFLÖSUNG)** in accordance with the

„Standard Methods of the DGHM for testing of chemical disinfection processes" (Status: 2001-09-01) I hereby issue the following evaluation of the results from the test report 2004-11-05 (SN 3979):

Results of the in vitro-tests

On the basis of the results of the qualitative suspension tests, the results obtained with the 4 test strains in the following quantitative suspension tests were evaluable.

The quantitative suspension tests were carried out under clean condition in spread plate technique for germ detection.

DÜRR SYSTEM-HYGIENE FD 350 DESINFEKTIONSTÜCHER (WIRKSTOFFLÖSUNG) resulted in sufficient reductions (5 lg. units of the test bacteria or 4 lg. units of C. albicans)

under clean condition

in 50 % within 30 seconds

Results under practical conditions

The efficacy of the disinfectant **DÜRR SYSTEM-HYGIENE FD 350 DESINFEKTIONSTÜCHER (WIRKSTOFFLÖSUNG)** was tested under clean condition.

Under this condition the

concentrate showed within 1 minute

a sufficient efficacy against the test strains S.aureus, E.hirae, P.aeruginosa and C. albicans.

Application recommendations for
DÜRR SYSTEM-HYGIENE FD 350 DESINFEKTIONSTÜCHER (WIRKSTOFFLÖSUNG)
for surface disinfection without mechanical action

According to the results obtained, **DÜRR SYSTEM-HYGIENE FD 350 DESINFEKTIONSTÜCHER (WIRKSTOFFLÖSUNG)** complies with the

„Requirements Specification for the Admission of Chemical Disinfection Processes in the DGHM Disinfectant List" (Status: 2002-02-04)

under clean condition as

concentrated within 1 minute.

Prof. Dr. med. H.-P. Werner

FD350の表面域への化学的消毒薬としての有効性検証

Dr. E. Marth 2004/11/10

Investigation and evaluation of surface disinfectants of FD350

ドイツ応用衛生協会（DGHM）基準に従い本液の表面域消毒薬としての菌および真菌への効果を検証した結果、有効成分1-プロパノール32g／100g及びエタノール26g／100g 含有のFD350（100%濃度/未希釈）は1分間の作用時間で病院および一般診療の院内感染予防に有効であることが証明された。

Prof. Egon MARTH, MD. PhD.

Medical Specialist in Hygiene and Laboratory Medicine

Universitätspl.4, A-8010 GRAZ; Austria
Phone: +43 (0316)380 ext. 4360; Fax: +43 (0316)380 ext. 9648
E-Mail: egon.marth@meduni-graz.at

OROCHEMIE
Dürr+Pflug GmbH & Co.KG.

Max – Planck – Straße 27
D – 70806 Kornwestheim

E X P E R T I S E

The product

„DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)“

was investigated for potential as a surface disinfectant according to the "Standard Methods" for the investigation and evaluation of chemical disinfectants (German Society of Hygiene and Microbiology, Sept. 1st, 2001)

Graz, November 10th, 2004

General specifications regarding the product
"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"

The product was to be tested under low challenge according to the „Standard Methods" for the investigation of chemical disinfectants (German Society of Hygiene and Microbiology, Sept. 1st, 2001)

Active ingredients per 100g as specified by the manufacturer:

32g 1-Propanol
26g Ethanol

Appearance and odour:

Clear, colourless liquid, alcoholic, slightly scented.

General conditions, i.e. regulation of room temperature and water hardness, have been observed.

Batch No: 001

Date of manufacture: 20.01.2004

pH-values, measured by glass electrode:

undiluted	pH = 6,85
75%	pH = 7,80
50%	pH = 7,68
25%	pH = 7,60
10%	pH = 7,55
5%	pH = 7,60

EVALUATION

General specifications regarding the tested product
„DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)“
(Batch-No. etc. see page 2)

1 Evaluation of the bacteriostatic and fungistatic efficacy and of suitable inactivating substances:

Based on the ingredients of the product, several neutralizing substances were tested. The combination of CSL + 3% Tween 80 + 3% Saponin + 0,1% Cystein + 0;1% Histidin proved to be acceptable.
This combination was used in all tests.
The minimal growth inhibiting concentration of the tested product in the dilution test was 5.0% for E.coli und P.aeruginosa, 7,5% for S.aureus, E.faecium, E.hirae and 15% for C.albicans.

2 Evaluation of the bactericidal and fungicidal efficacy in the qualitative suspension test (under low challenge)

The minimal 1 minute contact bactericidal/fungicidal concentration of the tested product was 50% for all tested organisms.

3 Evaluation of the bactericidal and fungicidal efficacy in the quantitative suspension test (under low challenge)

The required 5 log reduction factor after a 1 minute contact is reached at a product concentration of 50% for S.aureus, E.hirae und P.aeruginosa under low challenge (0,03% albumen).The required 4 log reduction after a 1 minute contact for Candida albicans is reached at a product concentration of 50% under low challenge (0,03% albumen).

4 Surface disinfection – practical testing
Evaluation of the bactericidal and fungicidal efficacy on non porous surfaces (under low challenge)

Test surface: metal discs, contaminated with S. aureus, E. hirae, P aeruginosa and C. albicans.
According to the actual reduction rates (product specific), determined for each of the tested organisms the tested product is considered efficient as a surface disinfectant used undiluted with a contact time of 1 minute.

CONCLUSION

According to the requirements of the „Standard Methods“ (Sept 1st, 2001) of the German Society for Hygiene and Microbiology for the testing of chemical disinfectants, the tested product

„DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)“

has been proved to be a suitable preparation as a surface disinfectant for the prophylaxis of nosocomial infections in the hospital and the general practice if used

undiluted for 1 minute

(O.Univ.Prof.DDr.E.MARTH)

FD350の結核菌（マイコバクテリウム）への機械的作業下での表面除菌効能性検証

PD Dr. med. H.-P. Werner 2004/11/06

Surface disinfection with mechanical action Tuberculocidal (M. terrae) efficacy clean conditions

DGHMのガイドラインに従い、衛生状況環境下における定量的浮遊実験と診療を想定した実使用試験をマイコバクテリウムに対して行った結果、FD350（100%濃度/未希釈）は機械的作業で15秒の作用時間で十分な有効性を示し、以上の試験結果はVAH消毒委員会による消毒プロセスの認証の評価基準を満たしていることが実証された。

PROF. DR. MED. H. - P. WERNER
FACHARZT FÜR HYGIENE

c/o HygCen Centrum für Hygiene und
medizinische Produktsicherheit GmbH
Bornhövedstraße 78
D-19055 Schwerin
Tel.: +49 (0)385 / 56 82 65
Fax: +49 (0)385 / 56 82 67
E-Mail: hpwerner@hygcen.de

Prof. Dr. H.-P. Werner · c/o HygCen GmbH · Bornhövedstr. 78 · D-19055 Schwerin

orochemie GmbH + Co KG

Max-Planck-Straße 27

D-70806 Kornwestheim

2008-10-29

DÜRR SYSTEM-HYGIENE FD 322 Schnelldesinfektion
Surface Disinfection with mechanical action
Tuberkulocidal (M. terrae) efficacy
Clean conditions

EXPERTISE

After testing the disinfectant **DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher** in accordance with the

„Standard Methods of the DGHM for testing of chemical disinfection processes" (Status: 2001-09-01)

I hereby issue the following evaluation of the results from the test report 2008-10-29 (SN 8047):

Results of the in vitro-tests

On the basis of the results of the quantitative suspension tests, the results of **DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher** obtained (4. lg. of test strain M. terrae) under clean conditions were evaluable.

in 89 % within 15 secounds

Results under practical conditions

The efficacy of the disinfectant **DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher** was tested **under clean condition.**

Under this condition resulted

the concentrate within 15 secounds

a sufficient efficacy against the test strains M. terrae.

Application recommendations for
DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher
for surface disinfection with mechanical action

According to the results obtained, **DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher** complies with the

„Requirements Specification for the Admission of Chemical Disinfection Processes" of the commission of VAH

under **clean conditon** against test strain M. terrae

the concentrate within 15 secounds.

Prof. Dr. med. H.-P. Werner

FD350の結核菌への非機械的作業下での表面除菌効能性検証

PD Dr. med. H.-P. Werner 2004/11/24

Surface disinfection without mechanical action Tuberculocidal efficacy clean and dirty conditions

DGHMのガイドラインに従い、衛生状況下及び汚染状況下における定量的浮遊実験と診療を想定した実使用試験をマイコバクテリウムに対して行った結果、FD350（100%濃度/未希釈）は非機械的作業で、衛生環境下／30秒間、汚染状況下／1分間の作用時間で十分な有効性を示し、以上の試験結果はVAH消毒委員会による消毒プロセスの認証の評価基準を満たしていることが実証された。

PROF. DR. MED. H. - P. WERNER
FACHARZT FÜR HYGIENE

c/o HygCen Centrum für Hygiene und
medizinische Produktsicherheit GmbH
Bornhövedstraße 78
D-19055 Schwerin
Tel.: +49 (0)385 / 56 82 65
Fax: +49 (0)385 / 56 82 67
E-Mail: hpwerner@hygcen.de

Prof. Dr. H.-P. Werner · c/o HygCen GmbH · Bornhövedstr. 78 · D-19055 Schwerin

Orochemie
DÜRR + PFLUG GmbH + Co KG
Max-Planck-Straße 27

D- 70806 Kornwestheim

2004-11-24

DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)
Surface disinfection without mechanical action
Tuberculocidal efficacy
Clean and dirty conditions

EXPERTISE

After testing the disinfectant **DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)** in accordance with the

„Standard Methods of the DGHM for testing of chemical disinfection processes"
(Status: 2001-09-01)

I hereby issue the following evaluation of the results from the test report 2004-11-24 (SN 3979):

Results of the in vitro-tests

The quantitative suspension tests were carried out **under clean and dirty conditions.**

DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) resulted in sufficient reductions (4 log. units) of M. terrae **under clean and dirty conditions**

in 75 % within 30 seconds.

Results under practical conditions

The efficacy of the disinfectant **DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)** was tested in these test series also **under clean and dirty conditions.**

Under clean conditions the test product showed as concentrate and 75 % within 30 seconds a sufficient efficacy against the test strain M. terrae.

Under dirty conditions the same effect was obtained within 1 minute.

Application recommendations for
DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)
for surface disinfection without mechanical action

According to the results obtained, **DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)** complies with the

„Requirements Specification for the Admission of Chemical Disinfection Processes"
of the Disinfectant commission of the VAH.

under clean conditions against M. terrae

concentrated within 30 seconds and

under dirty conditions

concentrated within 1 minute.

Prof. Dr. med. H.-P. Werner

FD350のマイコバクテリウムへの表面除菌効能検証

Dr. E. Marth 2005/01/20

Investigation of surface disinfectant without scrubbing and under low challenge with Mycobacterium terrae.

DGHMのガイドラインに従い、0.03%アルブミン汚染状況下におけるマイコバクテリウムへの効能を検証する定量的浮遊実験を行った結果、FD350（50%濃度／2倍希釈）は20秒間の作用時間で要求値である4logの減少に達した。また診療を想定した実使用試験では、マイコバクテリウムに汚染された0.03%アルブミンの付着した金属盤表面においてFD350（100%濃度／未希釈）は30秒の作用時間で十分な除菌効能を示した。以上の試験結果より、有効成分1-プロパノール32g／100g及びエタノール26g／100g　含有のFD350（100%濃度／未希釈）は擦る作業を伴わない30秒の接触時間で0.03%アルブミン汚染状況下のマイコバクテリウムに対して適切な除菌効果が証明された。

Prof. Egon MARTH, MD. PhD.

Medical Specialist in Hygiene and Laboratory Medicine

Universitätspl.4, A-8010 GRAZ; Austria
Phone: +43 (0316)380 ext. 4360; Fax: +43 (0316)380 ext. 9648
E-Mail: egon.marth@meduni-graz.at

OROCHEMIE
Dürr+Pflug GmbH & Co.KG.

Max – Planck – Straße 27
D – 70806 Kornwestheim

EXPERTISE

The product

„DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)“

was investigated for potential as a surface disinfectant without scrubbing and under low challenge with Mycobacterium terrae.

Active ingredients per 100g specified by the manufacturer:
32g 1-Propanol
26g Ethanol

Appearance and odour:
Clear, colourless liquid, alcoholic, slightly scented.

The product was to be tested according to the „Standard Methods“ for the investigation of chemical disinfectants (German Society of Hygiene and Microbiology, Sept.1st, 2001)

Graz, January 20th, 2005

EVALUATION

1. **Evaluation of the tuberculocidal efficacy in the quantitative suspension test (under low challenge).**
   The required 4 log reduction factor at 20 seconds contact is reached at a product concentration of 50% for M.terrae under low challenge (0,03% albumen).

2. **Surface disinfection – practical testing**
   Evaluation of the tuberculocidal efficacy, non porous surfaces (under low challenge).
   Tested surface: metal discs
   Contaminated with M. terrae
   According to the actual reduction rates (Product specific, determined for the rested organism) the tested product "DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)" in considered efficient as a surface disinfectant for M. terrae used undiluted with a contact time of 30 seconds.

CONCLUSION

Tested under practical working conditions

„DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)“

in undiluted application at a 30 seconds contact

has been proved to be a suitable preparation as a surface disinfectant for „Mycobakterium terrae“ under low challenge without scrubbing effect.

O.Univ.-Prof.DDr.E.MARTH

FD350の定量的浮遊試験における殺菌性評価

HygCen Dr. med. H.-P. Werner and Kathrin Naujox 2009/12/03

Quantitative Suspension test for the evaluation of bactericidal activity

FD350の殺菌力評価のために、EN13727に準じて医療領域における希釈中和法を用いた定量的浮遊試験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌に対して標準硬度の20±1℃の水を用いて本液を、80%・50%・25%の3種の濃度にて希釈し30秒・1分・5分の作用時間で評価を行った結果、黄色ブドウ球菌、腸内連鎖球菌、緑膿菌の高負荷汚染状況下（0.3%牛アルブミン+0.3%ヒツジ赤血球）において80%濃度及び50%濃度のFD350は20℃の環境下で30秒間の作用時間で十分な有効性を示した。

HYGICEN®
Centrum für Hygiene
und medizinische Produktsicherheit

HygCen GmbH • Postfach 11 01 35 • D-19001 Schwerin

orochemie GmbH + Co. KG
Max-Planck-Straße 27

D- 70806 Kornwestheim

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Verzeichnis: www.aks-hannover.de
Staatliche Akkreditierungsstelle Hannover

2009-12-03
Prof. We/ku

DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher
prEN 13727 (2009-04)
Quantitativer Suspensionstest – Bakterizide Wirksamkeit
(Phase 2, Stufe 1)
DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher
prEN 13727 (2009-04)
Quantitative Suspension test for the evaluation of bactericidal activity
(phase 2, step 1)

PRÜFBERICHT/*TEST REPORT*

Proben-Nr. / *Identification of the test laboratory:*	SN 9605
Prüfprodukt / *test product:*	DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher
Chargen-Bez. / *batch no.:*	0906906
Auftraggeber / *manufacturer:*	orochemie GmbH + Co. KG
Auftragsdatum / *date of order:*	2009-11-05
Materialeingang / *date of delivery*:	2009-11-11
Vom Hersteller empfohlenes Verdünnungsmittel / *product diluent recommended by the manufacturer for use:*	konzentrierte Anwendung / *concentrated application*
Aussehen / *appearance*:	klare, farblose Flüssigkeit / *clear, colourless liquid*
Geruch / *odour*:	alkoholisch / *alcoholic*
Lagerbedingungen / *storage conditions*:	gemäß Herstellerangaben / *those of the manufacturer*
Inhaltsangaben per 100 g / *active substances per 100 g*:	32 g 1-Propanol 26 g Ethanol

Prüfinstitut
HygCen Centrum für Hygiene und medizinische Produktsicherheit GmbH
Bornhövedstraße 78 · D-19055 Schwerin
Telefon: +49 (0) 385 56 82 65
Telefax: +49 (0) 385 56 82 67
E-Mail: info@hygcen.de
Internet: www.hygcen.de

Deutsche Apotheker- u. Ärztebank BLZ 300 606 01 Konto 0005 5786 98
Deutsche Bank AG Schwerin BLZ 130 700 24 Konto 3 184 645

Bei Überweisungen aus dem Ausland:
Deutsche Apotheker- u. Ärztebank IBAN DE 50 3006 0601 0005 5786 98
BIC DAAEDEDD

Geschäftsführerin Dipl.-Ing. (FH) Margrit Werner · Amtsgericht Schwerin HRB 4792 · UST.-Nr.: DE 178599849 · Steuer-Nr.: 090/110/03882

HYGICEN® Centrum für Hygiene und medizinische Produktsicherheit GmbH

Prüfmethode / *test method:*	**prEN 13727 (2009-04)** **Quantitativer Suspensionsversuch zur Bestimmung der bakteriziden Wirkung im humanmedizinischen Bereich** **(Phase 2, Stufe 1)** ***prEN 13727 (2009-04)*** ***Quantitative suspension test for the evaluation of bactericidal activity in the medical area*** ***(phase 2, step 1)***
Prüfzeitraum / *period of analysis*:	2009-11-13 to 2009-11-15
Prüftemperatur / *test temperature*:	20 °C ± 1 °C
Prüfkonzentrationen / *product test concentrations:*	80 %, 50 %, 25 % (v/v) end concentrations
Einwirkzeiten / *contact times*:	½ min., 1 min., 5 min.
Auszählverfahren / *counting procedure:*	Plattengussverfahren */ pour plate method*
Inkubation / *incubation*:	36 °C ± 1 °C – 48 h
Probenverdünnungsmittel / *diluent used for product test solution*:	destilliertes Wasser / *distilled water*
Methode der Neutralisation / *method of neutralisation*:	Verdünnungs-Neutralisation / *dilution neutralisation*
Stabilität und Aussehen des Prüfproduktes während der Prüfung / *stability and appearance of the mixture during the procedure:*	kein Niederschlag oder Ausfällungen / *no flocculants or precipitation*
Neutralisationsmittel/Spülflüssigkeit / *neutralizer/rinsing liquid*:	3,0 % Tween 80 + 3,0 % Saponin + 0,1 % Histidin + 0,1 % Cystein / destilliertes Wasser / *3.0 % polysorbate 80 + 3.0 % saponine + 0.1 % histidine + 0.1 % cysteine / distilled water*
Belastungssubstanz / *interfering substance*:	0,3 % Rinderalbumin + 0,3 % Schaf-Erythrozyten (hohe Belastung) */ 0.3 % bovine albumin + 0.3 % sheep erythrocytes (dirty conditions)*
Prüfkeime / *test strains*:	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442

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Schlussbestimmung /
Conclusion:

Nach prEN 13727 (2009-04) weist die Charge 0906906 des Produktes DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher eine bakterizide Wirkung unter hoher Belastung (0,3 % Rinderalbumin + 0,3 % Schaf-Erythrozyten) bei 20 °C nach ½ Minute bei Verdünnung auf 80 % und 50 % (v/v) gegen die Testkeime *Staphylococcus aureus, Enterococcus hirae* und *Pseudomonas aeruginosa* auf.

According to prEN 13727 (2009-04) the batch 0906906 of product DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher possesses a bactericidal activity under dirty conditions (0.3 % bovine albumin + 0.3 % sheep-erythrocytes) at 20 °C in ½ minute for the referenced strains Staphylococcus aureus, Enterococcus hirae and Pseudomonas aeruginosa when diluted at 80 % and 50 % (v/v).

Archivierung:

Eine Ausfertigung des Berichtes wird zusammen mit den Rohdaten im Archiv des Auftragnehmers aufbewahrt.

Archive:

The raw data with respect to this test and a copy of the report will be maintained by HygCen in the archive.

Hinweis:

Die Prüfergebnisse beziehen sich ausschließlich auf den genannten Prüfgegenstand. Auszugsweise Wiedergabe dieses Berichtes nur mit schriftlicher Genehmigung der HygCen GmbH.

Information:

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Prof. Dr. med. H.-P. Werner
Manager of scientific-technical affairs

Kathrin Naujox
Department manager

FD350の定量的浮遊試験における殺菌性検証

HygCen Dr. med. H.-P. Werner and Kathrin Naujox 2005/02/08

Quantitative Suspension test - bactericidal activity

EN13727に準じて、FD350の衛生状況環境下における定量的浮遊実験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌に対して行った結果、有効成分1-プロパノール32g／100g及びエタノール26g／100g　含有のFD350（50%濃度／2倍希釈）は衛生状況下（00.3%アルブミン）において、30秒間の作用時間で十分な有効性を示した。

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orochemie
Dürr + Pflug GmbH + Co KG
Max-Planck-Str. 27

D- 70806 Kornwestheim

2005-02-08
Prof. We/ku

DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher
EN 13727 (DRAFT FOR REVISION) (September 2004)
quantitative suspension test – bactericidal activity
(phase 2, step 1)

TESTREPORT

Identification of the test laboratory:	SN 3979
Test product:	DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher
Batch number:	001 (SQ 322-1)
Manufacturer:	orochemie
Date of order:	2005-01-21
Date of delivery:	2004-07-09
Appearance:	clear, colourless liquid
Odour:	alcoholic, aromatic
Active substances per 100 g:	32.0 g 1-propanol 26.0 g ethanol

HygCen Centrum für Hygiene und medizinische Produktsicherheit GmbH
Bornhövedstraße 78
(Eingang W.-Rathenau-Str.) ☑Postfach 110135
D-19055 Schwerin D-19001 Schwerin
Telefon: +49 (0) 385 56 82 65
+49 (0) 385 59 83 74
Telefax: +49 (0) 385 56 82 67
E-Mail: info@hygcen.de
Internet: www.hygcen.de
Dt. Apotheker- und Ärztebank BLZ 120 906 40 Konto 0 005 578 698
Deutsche Bank AG Schwerin BLZ 130 700 24 Konto 3 184 645
Mainzer Volksbank BLZ 551 900 00 Konto 396 317 018
Steuer-Nr.: 090/110/03882

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Conclusion: According to EN 13727 (DRAFT FOR REVISION) (09/2004) the batch number 001 of product DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher possesses a bactericidal activity under clean conditions (0.03 % albumine) in 30 seconds for the referenced strains *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541 and *Pseudomonas aeruginosa* ATCC 15442 when diluted at 50 % (v/v) in distilled water.

Archive: **The raw data with respect to this test and a copy of the report will be maintained by HygCen in the archive.**

HygCen
Centrum für Hygiene und
medizinische Produktsicherheit GmbH

Prof. Dr. med. H.-P. Werner
Manager of technical affairs

CENTRUM FÜR HYGIENE UND MEDIZINISCHE PRODUKTSICHERHEIT GMBH HYGCEN

Kathrin Naujox
Department manager

FD350の医療領域での定量的浮遊試験における殺真菌性評価

HygCen Dr. med. H.-P. Werner and Kathrin Naujox 2009/12/03

Quantitative Suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area

FD350の希釈中和法を用いた殺真菌力評価のために、医療領域における定量的浮遊試験をEN13624に準じてカンジダ・アルビカンスに対して標準硬度の30±1℃の水を用いて本液を、80%・50%・25%の3種の濃度にて希釈し30秒・1分・5分の作用時間で評価を行った結果、20℃の真菌（カンジダ・アルビカンス）汚染状況下（0.3%牛アルブミン+0.3%ヒツジ赤血球）においてFD350（80%濃度/1.25倍希釈）は30秒間の作用時間で十分な有効性を示した。

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HygCen GmbH • Postfach 11 01 35 • D-19001 Schwerin

orochemie GmbH + Co. KG
Max-Planck-Straße 27

D- 70806 Kornwestheim

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AKS Akkreditierung: AKS-PL-21301
Verzeichnis: www.aks-hannover.de
Staatliche Akkreditierungsstelle Hannover

2009-12-03
Prof. We/ku

DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher
prEN 13624 (2009-04)
Quantitativer Suspensionsversuch – levurozide (*C. albicans*) Wirkung
(Phase 2, Stufe 1)
DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher
prEN 13624 (2009-04)
Quantitative Suspension test – yeasticidal (C. albicans) efficacy
(Phase2, step1)

PRÜFBERICHT/*TEST REPORT*

Proben-Nr. / *Identification of the test laboratory:*	SN 9605
Prüfprodukt / *test product:*	DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher
Chargen-Bez. / *batch no.:*	0906906
Auftraggeber / *manufacturer:*	orochemie GmbH + Co. KG
Auftragsdatum / *date of order:*	2009-11-05
Materialeingang / *date of delivery*:	2009-11-11
Vom Hersteller empfohlenes Verdünnungsmittel / *product diluent recommended by the manufacturer for use:*	konzentrierte Anwendung / *concentrated application*
Aussehen / *appearance*:	klare, farblose Flüssigkeit / *clear, colourless liquid*
Geruch / *odour*:	alkoholisch / *alcoholic*
Lagerbedingungen / *storage conditions*:	gemäß Herstellerangaben / *those of the manufacturer*
Inhaltsangaben per 100 g / *active substances per 100 g*:	32 g 1-Propanol 20 g Ethanol

Prüfinstitut
HygCen Centrum für Hygiene und medizinische Produktsicherheit GmbH
Bornhövedstraße 78 · D-19055 Schwerin
Telefon: +49 (0) 385 56 82 65
Telefax: +49 (0) 385 56 82 67
E-Mail: info@hygcen.de
Internet: www.hygcen.de

Deutsche Apotheker- u. Ärztebank BLZ 300 606 01 Konto 0 005 578 698
Deutsche Bank AG Schwerin BLZ 130 700 24 Konto 3 184 645

Bei Überweisungen aus dem Ausland:
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Methodik / *Method*:	**prEN 13624 (2009-04)** **Quantitativer Suspensionsversuch zur Prüfung der fungiziden oder levuroziden Wirkung im humanmedizinischen Bereich (Phase 2, Stufe 1) /** ***prEN 13624 (2009-04)*** ***Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area (phase 2, step 1)***
Prüfzeitraum / *period of analysis*:	2009-11-13 – 2009-11-15
Prüftemperatur / *test temperature*:	20 °C ± 1 °C
Prüfkonzentrationen / *product test concentrations:*	80 %, 50 %, 25 % (v/v) end concentrations
Einwirkzeiten / *contact times*:	½ min. , 1 min., 5 min.
Auszählverfahren / *counting procedure:*	Plattengussverfahren */ pour plate method*
Inkubation / *incubation*:	48 h - 30 °C ± 1 °C
Probenverdünnungsmittel / *diluent used for product test solution*:	destilliertes Wasser */ distilled water*
Methode der Neutralisation / *method of neutralisation*:	Verdünnungs-Neutralisation / *dilution neutralisation*
Stabilität und Aussehen des Prüfproduktes während der Prüfung / *stability and appearance of the mixture during the procedure:*	kein Niederschlag oder Ausfällungen / *no flocculants or precipitation*
Neutralisationsmittel / *neutralizer*:	3,0% Tween 80 + 3,0% Saponin + 0,1% Histidin + 0,1% Cystein / *3.0% polysorbate 80 + 3.0% saponine + 0.1% histidine + 0.1% cysteine*
Belastungssubstanz / *interfering substance*:	0,3 % Rinderalbumin + 0,3 % Schaf-Erythrozyten (hohe Belastung) */ 0.3 % bovine albumin + 0.3 % sheep erythrocytes (dirty conditions)*
Prüfkeim / *test strain*:	*Candida albicans* ATCC 10231

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Schlussfolgerung / *Conclusion:*

Nach prEN 13624 (2009-04) weist die Charge 0906906 des Produktes DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher bei 20°C nach ½ Minute unter hoher Belastung (0,3 % Albumin + 0,3 % Schaf-Erythrozyten) bei Verdünnung auf 80 % (v/v) in destilliertem Wasser eine levurozide Wirkung gegen den Testkeim *Candida albicans* auf.

According to prEN 13624 (2009-04) the batch 0906906 of the product DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher possesses a yeasticidal activity at 20°C in ½ minute under dirty conditions (0.3 % albumin + 0.3 % sheep erythrocytes) for the referenced strain Candida albicans when diluted at 80 % (v/v) in distilled water.

Archivierung: **Eine Ausfertigung des Berichtes wird zusammen mit den Rohdaten im Archiv des Auftragnehmers aufbewahrt.**

Archive: ***The raw data with respect to this test and a copy of the report will be maintained by HygCen in the archive.***

Hinweis: Die Prüfergebnisse beziehen sich ausschließlich auf den genannten Prüfgegenstand. Auszugsweise Wiedergabe dieses Berichtes nur mit schriftlicher Genehmigung der HygCen GmbH.

Information: *The test results are valid for the named test subject only. Reproduction of any part of this report requires the written permission HygCen GmbH.*

Prof. Dr. med. H.-P. Werner
Manager of scientific-technical affairs

Kathrin Naujox
Department manager

FD350の定量的浮遊試験における殺真菌性評価

HygCen Dr. med. H.-P. Werner and Kathrin Naujox 2005/01/14

Quantitative Suspension test for evaluation of fungicidal activity

FD350の殺真菌力評価のために、EN13624に準じて定量的浮遊試験をカンジダ・アルビカンスに対して行った結果、20℃の衛生状況下において有効成分1-プロパノール32g／100g及びエタノール26g／100g 含有のFD350（50%濃度/2倍希釈）は30秒間の作用時間で十分な有効性を示した。

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HygCen GmbH • Postfach 11 01 35 • D-19001 Schwerin

orochemie
Dürr + Pflug GmbH + Co KG
Max-Planck-Str. 27

D- 70806 Kornwestheim

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2005-01-14
Prof. We/ku

Dürr System-Hygiene FD 350 Desinfektionstücher (Wirkstofflösung)
DIN EN 13624 (February 2004)
Quantitative suspension test for evaluation of fungicidal activity
(phase 2/step 1)

TESTREPORT

Product:	Dürr System-Hygiene FD 350 Desinfektions-tücher (Wirkstofflösung)
Identification of the test laboratory:	SN 3979
Date of delivery:	2004-07-09
Batch number :	001
Manufacturer:	orochemie
Storage conditions:	those of the manufacturer
Active substance:	32.0 g 1-propanol 26.0 g ethanol
Appearance:	clear colourless liquid
Odour:	alcoholic aromatic

HygCen Centrum für Hygiene und medizinische Produktsicherheit GmbH
Bornhövedstraße 78
(Eingang W.-Rathenau-Str.) D-19055 Schwerin
Postfach 110135 D-19001 Schwerin
Telefon: +49 (0) 385 56 82 65
+49 (0) 385 59 83 74
Telefax: +49 (0) 385 56 82 67
E-Mail: info@hygcen.de
Internet: www.hygcen.de
Dt. Apotheker- und Ärztebank BLZ 120 906 40 Konto 0 005 578 698
Deutsche Bank AG Schwerin BLZ 130 700 24 Konto 3 184 645
Mainzer Volksbank BLZ 551 900 00 Konto 396 317 018
Steuer-Nr.: 090/110/03882

HYGCEN® Centrum für Hygiene und medizinische Produktsicherheit GmbH

Conclusion: According to DIN EN 13624 (February 2004) the batch 001 of product Dürr System-Hygiene FD 350 Desinfektionstücher (Wirkstofflösung) possesses a fungicidal activity at 20 °C under clean conditions in 30 seconds for the referenced strain *Candida albicans* when diluted at 50 % (v/v) in distilled water.

Archive: **The raw data with respect to this test and a copy of the report will be maintained by HygCen in the archive.**

HygCen
Centrum für Hygiene und
medizinische Produktsicherheit GmbH

Prof. Dr. med. H.-P. Werner
Manager of scientific-technical affairs

K. Naujox
Department manager

FD350の定量的浮遊試験における殺結核菌（マイコバクテリウム）効能検証

HygCen Dr. med. H.-P. Werner and Kathrin Naujox 2005/02/17

Quantitative Suspension test for evaluation of mycobactericidal efficacy

FD350の殺結核菌効能検証のために、EN14348に準じて定量的浮遊試験をマイコバクテリウム・テラエ及びマイコバクテリウム・アビウムに対して行った結果、衛生状況下（00.3%アルブミン）において、有効成分1-プロパノール32g／100g及びエタノール26g／100g 含有のFD350（80%濃度/1.25倍希釈）は30秒間の作用時間で十分な有効性を示した。

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orochemie
Dürr + Pflug GmbH + Co KG
Max-Planck-Str. 27

D- 70806 Kornwestheim

2005-02-17
Prof. We/ku

DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)
prEN 14348 – quantitative suspension test, mycobactericidal efficacy
phase 2, step 1

TEST REPORT

Identification of the test laboratory:	SN 3979
Test product:	DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)
Batch no.:	001
Manufacturer:	orochemie
Date of order:	2004-07-07
Date of delivery:	2004-07-09
Storage conditions:	those of the manufacturer
Appearance:	clear, colourless fluid
Odour:	alcoholic, aromatic
Active substances per 100 g:	32.0 g 1-propanol 26.0 g ethanol

HygCen Centrum für Hygiene und
medizinische Produktsicherheit GmbH
Bornhövedstraße 78
(Eingang W.-Rathenau-Str.) ✉Postfach 110135
D-19055 Schwerin D-19001 Schwerin

Telefon: +49 (0) 385 56 82 65
+49 (0) 385 59 83 74
Telefax: +49 (0) 385 56 82 67
E-Mail: info@hygcen.de
Internet: www.hygcen.de

Dt. Apotheker- und Ärztebank BLZ 120 906 40 Konto 0 005 578 698
Deutsche Bank AG Schwerin BLZ 130 700 24 Konto 3 184 645
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Conclusion:

According to prEN 14348 (09/2002), the product DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) possesses a mycobactericidal activity under clean conditions (0.03 % albumine) for the referenced strains *Mycobacterium terrae* and *Mycobacterium avium* in 30 seconds when diluted at 80 % (v/v) in distilled water.

Archive:

The raw with respect to this test and a copy of the report will be maintained by HygCen in the archive.

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Centrum für Hygiene und
medizinische Produktsicherheit GmbH

Prof. Dr. med. H.-P. Werner
Manager of technical affairs

CENTRUM FÜR HYGIENE UND MEDIZINISCHE PRODUKTSICHERHEIT GMBH

K. Naujox
Department manager

FD350のワクシニアウイルス不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 2005/01/19

Vaccinia-virus efficacy of FD350 in a quantitative suspension test at 20℃

連邦健康管理局（BGA）およびドイツウイルス疾病管理協会（DVV）のガイドラインに従い、ワクシニアウイルスに対する不活性化効力の定量的浮遊試験を、100%濃度／未希釈の本液を用いて20℃±0.5℃で30秒・1分・2分・5分の作用時間にて評価を行った結果、FD350（100%濃度/未希釈）は30秒間の作用時間でワクシニアウイルスに対して十分な不活性化効力を示すことが実証された。

DR. JOCHEN STEINMANN
Wiss. techn. Leiter der
MikroLab GmbH

Norderoog 2
D-28259 Bremen

Tel.: +49 (421) 27819102
Fax: +49 (421) 2760283
http://www.mikrolab-gmbh.de
E-Mail: MikroLab.GmbH@t-online.de

2005-01-19
Dr. St/sbe

MikroLab GmbH, Norderoog 2, D-28259 Bremen

orochemie
Postfach 16 30

70798 Kornwestheim

vacciniavirus efficacy of DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) in a quantitative suspension test at 20°C

EXPERT OPINION

The virus-inactivating properties of the surface disinfectant DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) of orochemie against vacciniavirus strain Elstree was investigated by a quantitative suspension test published as a guideline of the Bundesgesundheitsamt (BGA, now Robert Koch-Institut) and the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (DVV, German Association for the Control of Virus Diseases). According to this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having virucidal efficacy if within the recommended exposure period the titre is reduced by 4 $\log_{10}$.
DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) was examined as 100.0% solution at 20°C ± 0.5°C. The exposure times were 0.5, 1.0, 2.0 and 5.0 minutes. After an exposure time of 30 seconds virus reduction exceeded 4 $\log_{10}$-steps in all assays. Therefore, it can be recommended to use the surface disinfectant DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) for the inactivation of vacciniavirus as follows:

undiluted 30 sec.

Dr. J. Steinmann

FD350のC型肝炎ウイルス不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 2004/12/29

BVDV efficacy of FD350 in a quantitative suspension test at 20℃

FD350のC型肝炎ウイルス不活性化を検証するため、連邦健康管理局（BGA）ドイツおよびウイルス疾病管理協会（DVV）のガイドラインに従い、定量的浮遊試験を代用ウイルスの牛ウイルス性下痢ウイルス（BVDV）に対して100%濃度／未希釈の本液を用いて30秒・60秒・120秒・300秒の作用時間で評価を行った結果、FD350(100%濃度/未希釈)は30秒間の作用時間で十分なウイルス不活性化効力を示したことからC型肝炎ウイルス不活性化に有効であることが実証された。

DR. JOCHEN STEINMANN

Wiss. techn. Leiter der
MikroLab GmbH

Norderoog 2
D-28259 Bremen

Tel.: +49 (421) 27819102
Fax: +49 (421) 2760283
http://www.mikrolab-gmbh.de
E-Mail: MikroLab.GmbH@t-online.de

2004-12-29
Dr. St/sbe

MikroLab GmbH, Norderoog 2, D-28259 Bremen

orochemie
Postfach 16 30

70798 Kornwestheim

BVDV efficacy of DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) in a quantitative suspension test at 20°C

EXPERT OPINION

The virus-inactivating properties of the surface disinfectant DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) of orochemie against bovine viral diarrhea virus (BVDV) was investigated by a quantitative suspension test according to the guideline of the Bundesgesundheitsamt (Federal Board of Health) and the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (German Association for the Control of Virus Diseases). BVDV was chosen as a surrogate virus for hepatitis C virus (HCV) since there is no animal model or tissue culture system for growing this virus. Testing this surrogate virus the possibility is created to give recommendations for the inactivation of HCV by the disinfectant.

According to this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having virucidal efficacy if within the recommended exposure period the titre is reduced by 4 $\log_{10}$.

DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) was examined as 100.0% solution. The exposure times were 30, 60, 120 and 300 seconds. After an exposure time of 30 seconds virus reduction exceeded 4 $\log_{10}$-steps in all assays. Therefore, summarizing the results of the experiments it can be recommended to use the surface disinfectant DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) for the inactivation of BVDV as follows:

concentrated **30 sec.**

Dr. J. Steinmann

FD350のアデノウイルス不活性化効力の検証

MikroLab GmbH, Dr.Jochen Steinmann 2005/01/19

Adenovirus efficacy of FD350 in a quantitative suspension test at 20℃

連邦健康管理局（BGA）およびドイツウイルス疾病管理協会（DVV）のガイドラインに従い、アデノウイルス5型に対する不活性化効力の定量的浮遊試験を、100%濃度／未希釈の本液を用いて30秒・1分・2分・5分の作用時間で評価を行った結果、FD350(100%濃度/未希釈)は30秒間の作用時間で十分なアデノウイルス不活性化効力を示すことが実証された。

DR. JOCHEN STEINMANN
Wiss. techn. Leiter der
MikroLab GmbH

Norderoog 2
D-28259 Bremen

Tel.: +49 (421) 27819102
Fax: +49 (421) 2760283
http://www.mikrolab-gmbh.de
E-Mail: MikroLab.GmbH@t-online.de

2005-01-19
Dr. St/sbe

MikroLab GmbH, Norderoog 2, D-28259 Bremen

orochemie
Postfach 16 30

70798 Kornwestheim

adenovirus efficacy of DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) in a quantitative suspension test at 20°C

EXPERT OPINION

The virucidal efficacy of the surface disinfectant DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) of orochemie against adenovirus type 5 strain adenoid 75 was investigated by a quantitative suspension test published as a guideline of the Bundesgesundheitsamt (BGA, Federal Board of Health, now Robert Koch-Institut) and the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (DVV, German Association for the Control of Virus Diseases). In this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having virucidal efficacy if within the recommended exposure period the titre is reduced by 4 $logs_{10}$.

DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) was examined as 100.0% solution. The exposure times were 0.5, 1.0, 2.0 and 5.0 minutes. After an exposure time of 30 seconds virus reduction exceeded 4 log_{10}-steps in all assays. Therefore, it can be recommended to use the surface disinfectant DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) for the inactivation of adenovirus as follows:

undiluted 30 sec.

Dr. J. Steinmann

FD350のポリオーマウイルスSV40への不活性化効力の検証

MikroLab GmbH, Dr.Jochen Steinmann 2005/06/16

Polyomavirus SV40 efficacy of FD350 in a quantitative suspension test at 20℃

連邦健康管理局（BGA）およびドイツウイルス疾病管理協会（DVV）のガイドラインに従い、アデノウイルス5型に対する不活性化効力の定量的浮遊試験を、100%濃度／未希釈の本液を用いて30秒・1分・2分・5分の作用時間で評価を行った結果、FD350(100%濃度/未希釈)は30秒間の作用時間で十分なアデノウイルス不活性化効力を示すことが実証された。

DR. JOCHEN STEINMANN
Wiss. techn. Leiter der
MikroLab GmbH

Norderoog 2
D-28259 Bremen

phone: +49 (421) 27819102
fax: +49 (421) 2760283
http://www.mikrolab-gmbh.de
E-Mail: MikroLab.GmbH@t-online.de

2005-06-16
Dr. St/sbe

MikroLab GmbH, Norderoog 2, D-28259 Bremen

orochemie
Postfach 16 30

70798 Kornwestheim

Polyomavirus (formerly papovavirus) SV 40 efficacy of DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher in a quantitative suspension test at 20°C

EXPERT OPINION

The virus-inactivating properties of the surface disinfectant DÜRR SYSTEM-HYGIENE 322 Desinfektionstücher of orochemie against polyomavirus SV 40 were investigated by a suspension test according to the guideline of the Bundesgesundheitsamt (BGA, now Robert Koch-Institut) and the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (DVV, German Association for the Control of Virus Diseases). In this quantitative suspension test, a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$.

DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher was examined undiluted at 20°C ± 1°C. The exposure times were 1, 2, 5 and 15 minutes. Due to the lack of guidelines simulating practical conditions, results of this quantitative suspension test lead to the recommendation to use the surface disinfectant DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher for inactivation of polyomavirus SV 40 as follows:

without protein load	**undiluted**	**5 min**
with protein load	**undiluted**	**15 min**

Dr. J. Steinmann

FD350のノロウイルス不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 2008/07/29

Effectiveness of FD350 against murine norovirus following EN14476:2007-02 under clean and dirty conditions

FD350のノロウイルス不活性化効力を検証するため、EN14476に準じて定量的浮遊試験を衛生環境下及び汚染状況下にてマウスノロウイルス(MNV)に対して100%濃度／未希釈の本液を用いて衛生環境および汚染状況下で30秒・1分・5分の作用時間で評価を行った結果、FD350（100%濃度/未希釈）はマウスノロウイルス(MNV）に対して衛生環境、汚染状況下共に1分間の作用時間で十分なウイルス不活性化効力を示すことが実証された。

Dr. Jochen Steinmann
Wiss. Techn. Leiter der
Mikrolab GmbH

28259 Bremen
Norderoog 2

phon +49 (421) 27819102
fax +49 (421) 2760283
e-Mail: Mikrolab.GmbH@t-online.de

29.07.2008
Dr. St/sbe

Mikrolab GmbH Norderoog2 28259 Bremen

orochemie Dürr + Pflug GmbH + Co KG
Max-Planck-Straße 27

70798 Kornwestheim

Effectiveness of DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher against murine norovirus following EN 14476:2007-02 under clean and dirty conditions

EXPERT OPINION

This expert opinion is based on the test report O08ML623M dating 29.07.2008.

Effectiveness of the surface disinfectant DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher of orochemie against murine norovirus (MNV) were investigated by a quantitative suspension test following EN 14476:2007-02 under clean and dirty conditions.

MNV was chosen as a surrogate for human noroviruses since there is no system for virus replication available. Testing this surrogate virus the possibility is created to give recommendations for inactivation of human noroviruses by the disinfectant.

According to EN 14476:2007-02, a disinfectant is considered as having virucidal effectiveness if within the recommended exposure time the titre is reduced by ≥ four log_{10}-steps (inactivation ≥ 99.99 %).

The surface disinfectant DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher was examined undiluted. 0.5, 1.0 and 5.0 minutes were chosen as exposure times.
DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher reduced the virus titre by ≥ 4 log_{10}-steps after 60 seconds. Therefore, a virucidal activity against MNV under clean and dirty conditions was measured as follows:

undiluted **60 seconds**

Dr. J. Steinmann

FD350のアデノウイルス不活性化効力の検証

MikroLab GmbH, Dr.Jochen Steinmann 2005/03/24

Effectiveness of FD350 against adenovirus according to EN14476:2004E

FD350のアデノウイルス不活性化効力を検証するため、EN14476に準じて定量的浮遊試験をアデノウイルス5型に対して100%濃度／未希釈及び40%濃度／2.5倍希釈の本液を用いて衛生環境および汚染状況下で30秒・1分・2分・5分の作用時間で評価を行った結果、FD350（100%濃度/未希釈）はアデノウイルス5型に対して衛生環境、汚染状況下共に30秒間の作用時間で十分なウイルス不活性化効力を示すことが実証された。

Dr. Jochen Steinmann
Wiss. Techn. Leiter der
MikroLab GmbH

D-28259 Bremen
Norderoog 2

phone +49 (421) 27819102
fax +49 (421) 2760283
e-mail: Mikrolab.GmbH@t-online.de

2005-03-24
Dr. St/sbe

MikroLab GmbH Norderoog 2 28259 Bremen

orochemie
post box 16 30

D-70798 Kornwestheim

Effectiveness of DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) against adenovirus according to prEN 14476:2004 E

EXPERT REPORT

Effectiveness of the surface disinfectant DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) of orochemie was investigated against adenovirus type 5 according to the draft prEN 14476 (version 2004 E). This European standard describes a quantitative suspension test (phase 2, step 1), mixing one part by volume of test virus suspension, one part by volume of interfering substances and eight parts by volume of disinfectant. At specified contact times an aliquot is taken and residual infectivity determined.

According to prEN 14476:2004 E, a disinfectant is considered as having virucidal effectiveness if within the recommended exposure time the titre is reduced by ≥ four $\log_{10}$ (inactivation ≥99.99%).

The surface disinfectant DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) was examined undiluted (80%) and as 40% solution. The exposure times were 0.5, 1.0, 2.0 and 5.0 minutes.

After 30 seconds exposure time reduction factors of 5.12 (clean conditions) and 5.63 (dirty conditions) were measured.

Therefore, summarizing the results of the experiments it can be declared that the surface disinfectant DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) has virus-inactivating properties under clean and dirty conditions against adenovirus type 5 as following:

undiluted **30 seconds**

Dr. J. Steinmann

FD350のラットへの急性経口毒性試験

HARLAN Bioservice, Dr. E. Bien 2005/07/24

ACUTE ORAL TOXICITY Acute Toxic Class Method with FD350 in the rat

Acute Toxic Class Method（ATC）に準じて、FD350の急性経口毒性試験をオス3匹及びメス3匹のウィスターラットに対し、各ラットの体重に応じて本液2000mg/Kgを投与し、14日間の観察期間後に臨床的兆候、死亡率、体重増加または期間の病理学的変化に関して検査した結果、ラットの死亡は確認されず、また24時間後までに見られたオス及びメス1匹の呼吸音の変化以外は異常な臨床兆候も見られず、体重増加や病理学的変化もなかったことから、FD350は無毒薬液に分類された。

Harlan BIOSERVICE FOR SCIENCE

Report

ACUTE ORAL TOXICITY
Acute Toxic Class Method with
"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"
in the Rat

Study No.: **10-4-0187/02-04**

Sponsor: **orochemie**
Postfach 16 30
70798 Kornwestheim

Harlan
BIOSERVICE
FOR SCIENCE

Responsibilities

Study Director:	PD Dr. rer. biol. hum. habil. E. Bien (Dipl. Biologist, Toxicologist)
Test Performance:	K. J. Kühne, S. Poppe

Signature

Study Director

E. Bien — PD Dr. E. Bien

24. 1. 05 — Date

Harlan
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FOR SCIENCE

1.0 Summary

The acute oral toxicity of **"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"** was investigated according to the ATC method in one step using 3 male and 3 female rats.
Three female animals were given a single oral administration of the test article **"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"** at a dose of 2000 mg/kg. Since no female animal died after the administration, three male animals were treated subsequently with a single oral dose of **"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"** at 2000 mg/kg.
Clinical observations were carried out at regular intervals during the 14-day observation period. Body weights were determined immediately before treatment and on days 7 and 14 p.a.
Gross pathological examinations were carried out immediately at termination on all animals.

The following results were obtained:

- No animal died during the course of the 14-day observation period following the single oral dose of 2000 mg/kg.
- No abnormal clinical signs were observed, except of breathing sounds in one male and one female animal up to 24 h after treatment. Additionally activity and body tone were slightly decreased one male animal at 24 h after treatment.
- There was no influence of the treatment on the body weight development in all male and female animals during the 14-day observation period.
- Gross pathological examinations on day 14 p.a. did not reveal any findings.

According to the EEC Directive 2001/59, 6 August 2001 and the Gefahrstoffverordnung (GefStoffV) of 15 November 1999 (BGBl. I, p. 2233), the test article **"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"** can be classified as

"non-toxic",

since the oral LD_{50} value after 24 h and 14 days is expected to be higher than 2000 mg/kg in male and female Wistar rats.

FD350のラットへの急性経皮毒性試験

HARLAN Bioservice, Dr. E. Bien 2005/07/26

ACUTE DERMAL TOXICITY TEST OF FD350 in the rat

FD350の急性経皮毒性試験をウィスターラット（5匹のオス及びメス）に対して行い、各ラットに対し本液を2000mg／Kg経皮投与しラットの皮膚を試験品に24時間暴露した際の、紅斑及び浮腫のみの兆候を14日間に渡り検査した結果、ラットの死亡は確認されず、異常な臨床的兆候及び紅斑・浮腫はみられなかった。また14日の観察期間中、オスの体重増加はみられなかったが1匹のメスは7日後に体重減少がみられ、その他のメスに関してはわずかな体重増加が7日後までに見られた。14日目における病理学検査においてもすべてのラットに問題はみられなかった。

Harlan BIOSERVICE FOR SCIENCE

Report

ACUTE DERMAL TOXICITY TEST OF

"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"

in the Rat

Study No.: **10-4-0188/02-04**

Sponsor: **orochemie**
Postfach 16 30
70798 Kornwestheim

Harlan
BIOSERVICE
FOR SCIENCE

Responsibilities

Study Director: PD Dr. rer. biol. hum. habil. E. Bien
(Dipl. Biologist, Toxicologist)

Test Performance: K. J. Kühne, S. Poppe

Signature

Study Director

G. Bien — 26.1.05

PD Dr. E. Bien — Date

Harlan
BIOSERVICE
FOR SCIENCE

1.0 Summary

The acute dermal toxicity of **"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"** was investigated in one group of rats comprising 5 males and 5 females.

On the basis of the range finding test, the animals were given a single dermal administration of **"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"** at the dose of 2000 mg/kg. The skin was exposed to the test article for 24 hours.

Clinical observations were carried out at regular intervals during the 14-day observation period. Signs of erythema and oedema were evaluated once daily for 14 days. Body weights were determined immediately before treatment and on days 7 and 14 p.a.

Gross pathological examinations were carried out at study termination on all animals.

The following results were obtained:

- No animal died during the 14-day observation period.
- No abnormal clinical signs were observed.
- Neither signs of erythema nor oedema were observed.
- There was no influence of the treatment on the body weight development in male animals during the 14-day observation period. But in female animals, the body weight development was influenced by the treatment with the test article: reduced body weight (one female at 7 days after treatment) and decelerated weight gains (all other animals at both time points) were observed.
- Gross pathological examinations on day 14 p.a. did not reveal any findings in the rats.

FD350のモルモットへの皮膚感作試験

HARLAN Bioservice, Dr. E. Bien 2005/07/27

MAXIMISATION SENSITISATION TEST ACOORDING TO MAGNUSSON&KLIGMAN of FD350 in the Guinea Pig

Magnusson and Kligmanによって開発された試験法に従い、FD350の皮膚感作試験を被験物質投与群10匹，陰性（溶媒）対照群5匹に対して行い、本液の暴露2週間後、24時間・48時間での反応を観察した結果、すべてのモルモットにアレルギー性皮膚反応は見受けられなかったことから皮膚感作度は0%であり、ヨーロッパ経済共同体（EEC）指令2001/59EEC,2001年8月6日および1999年11月15日のGefahrstoffverordung（GefStofV）に基づき、FD350は非皮膚感作薬液であると証明された。

Harlan BIOSERVICE FOR SCIENCE

Report

MAXIMISATION SENSITISATION TEST ACCORDING TO MAGNUSSON & KLIGMAN OF

"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"

in the Guinea Pig

Study No.: **10-5-0190/02-04**

Sponsor: **orochemie**
Postfach 16 30
70798 Kornwestheim

Harlan
BIOSERVICE
FOR SCIENCE

Responsibilities

Study Director: PD Dr. rer. biol. hum. habil. E. Bien
(Dipl. Biologist, Toxicologist)

Test Performance: K. J. Kühne, S. Poppe

Signature

Study Director

E. Bien — PD Dr. E. Bien

27.1.05 — Date

Harlan
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1.0 Summary

The potential skin sensitising properties of the test article **"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"** were assessed in the guinea pig maximisation sensitisation test carried out as an adjuvant test according to the Magnusson & Kligman maximisation test method, using 10 test and 5 control animals in the main test.
Following the induction exposure to the test article or the vehicle, the animals of both groups were subjected two weeks later to a challenge exposure with the test article (100%) as well as the control article.
Responses to the challenge procedure were evaluated 24 and 48 h after the end of the exposure period.

Results

- No allergic skin reactions occurred in test animals 24 and 48 h after the end of the challenge procedure. The sensitisation rate was 0%.

- No findings were observed in control animals (reaction rate: 0%).

Evaluation

According to the EEC Directive 2001/59/EEC, 6 August 2001 and the Gefahrstoffverordnung (GefStoffV) of 15 November 1999 (BGBl. I, p. 2233), the the test article

"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"

can be classified as a **"non-sensitiser"** since no allergic responses were observed in test animals under the experimental conditions described.

FD350の皮膚腐食性インビトロ試験

RCC, Dipl. Biol. Krista Meurer and Dr. Wolfgang Voelkner 2005/02/04

IN VITRO SKIN CORROSION: Human skin model test with FD350

ヨーロッパ共同体（EC）指令2000/33/EC, EEC指令67/548/EEC及びOECDガイドラインに準じて、FD350の人体皮膚腐食性を2つの人体皮膚モデルを用いて2種類のテスト溶液、純水（ネガティブコントロール）・N8水酸化カリウム（ポジティブコントロール）を3分間及び1時間塗布し検証した。その結果、ネガティブコントロールのテストモデルの吸収度は3分間・1時間ともに要求値をはるかに超えており皮膚組織は良好であった。また、ポジティブコントロールのテストモデルは3分間ではネガティブコントロールと比較して23.1%の吸収率の誘発減少が見られ、1時間では4.9%の減少がみられたがこれはこのテスト法の基準内であった。FD350を塗布後、吸収値は3分後で103.5%減少したが50%以下になることはなく、1時間後では37.9%の減少で15%以下になることはなかった。以上のテスト結果からFD350は非皮膚腐食性薬液であると証明された。

RCC-CCR STUDY NUMBER 866400

IN VITRO SKIN CORROSION:
HUMAN SKIN MODEL TEST

WITH

DÜRR SYSTEM-HYGIENE FD 350
DESINFEKTIONSTÜCHER
(WIRKSTOFFLÖSUNG)

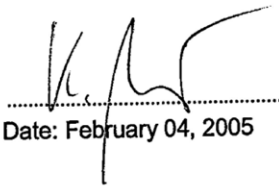
FINAL REPORT

Study Completion Date: February 04, 2005

RCC

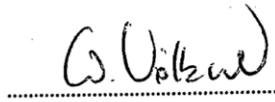
2.4 Project Staff Signatures

Study Director — Dipl. Biol. Krista Meurer



Date: February 04, 2005

Management — Dr. Wolfgang Völkner



Date: February 04, 2005

2.5 Guidelines

This study was conducted according to the procedures indicated by the following internationally accepted guidelines and recommendations:

Commission Directive 2000/33/EC, OJL136200, dated June 08, 2000, adopting the 27th time to technical progress the Dangerous Substances Directive 67/548/EEC, Annex V, part B40.

OECD Guideline for Testing of Chemicals: Draft Proposal for a new Guideline: 431; *In vitro* Skin Corrosion: Human Skin Model Test (OECD March 27, 2002).

2.6 Archiving

RCC Cytotest Cell Research GmbH will archive the following data for 15 years:

Raw data and a copy of the final report.

No data will be discarded without the Sponsor´s consent.

6 DISCUSSION

This *in vitro* study was performed to assess the corrosive potential of DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) by means of the Human Skin Model Test.

Two tissues of the human skin model EpiDerm™ were treated with either the test item, the negative or the positive control for 3 min and 1 hour, respectively.

50 µL of the liquid test item were applied to each tissue, spread to match the tissue size.

50 µL of either the negative control (deionised water) or the positive control (8.0 N KOH) were applied to each tissue.

After treatment with the negative control the absorbance values were well above the required acceptability criterion of 0.8 for both treatment intervals thus showing the quality of the tissues.

Treatment with the positive control induced a decrease in the relative absorbance as compared to the negative control to 23.1 % for the 3 minutes treatment interval and 4.9 % for the 1 hour treatment interval thus ensuring the validity of the test system.

After treatment with the test item DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) the relative absorbance values were decreased to 103.5 % after 3 minutes treatment but not to < 50%. After 1 hour treatment relative absorbance values were reduced to 37.9 % but not to < 15%. Therefore, the test item is considered non-corrosive.

7 CONCLUSION

In conclusion, it can be stated that in this study and under the experimental conditions reported, the test item DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) is **non-corrosive** to skin.

FD350のウサギへの急性眼刺激／腐食性試験

HARLAN Bioservice, Dr. E. Bien 2005/04/22

Acute Eye Irritation/Corrosion test of FD350 in the rabbit

FD350の急性眼刺激／腐食性試験を3匹のアルビノウサギに対して行い、本液（100%濃度/未希釈）を0.1ml左眼の結膜嚢に点眼し、未処置の眼は比較のために使用された。点眼1時間・24時間・48時間・72時間後に両目を検査し点眼開始から5日目まで毎日検査を継続した結果、1時間・24時間・48時間後すべてのウサギの結膜に標準値（グレード2）の発赤がみられ、2匹のウサギの発赤は72時間後及び4日後にも続いた。また1時間及び24時間後には軽微～標準値（グレード1～3）の結膜浮腫がすべてのウサギにみられ48時間後にも1匹のウサギの結膜浮腫は続いた。

Harlan
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FOR SCIENCE

Report

ACUTE EYE IRRITATION/CORROSION TEST OF
"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"
in the Rabbit

Study No.: **10-3-0112/02-05**

Sponsor: **orochemie**
Postfach 16 30
70798 Kornwestheim

その他の所見としては、点眼1時間後に2匹のウサギに軽微～標準値（グレード1～3）の膿がみられ残りの1匹にも24時間後同じ症状がみられた他、わずかなもしくは標準値の眼球の血管への注射では3匹中2匹に点眼24時間・48時間後、残りの1匹には72時間後に発赤が同様にみられた。すべての所見は可逆的で、視覚の変化は点眼5日後に見られず一般的な毒性効果はみられなかった。結膜の発赤レベルは1.33もしくは2.00、結膜浮腫レベルは0.33もしくは1.00とされ、以上の結果から24時間・48時間・72時間後の眼反応は2001/08/06付のEEC指令2001/59/EEC及び1999年11月15日付のGefahrstoffverordung（GefStofV）で定められた刺激性試験の基準値を下回っており、FD350は眼無刺激性薬液に分類された。

Harlan BIOSERVICE FOR SCIENCE

Responsibilities

Study Director:	PD Dr. rer. biol. hum. habil. E. Bien (Dipl. Biologist, Toxicologist)
Test Performance:	K.-J. Kühne

Signature

Study Director

E. Bien — PD Dr. E. Bien

22/4/2005 — Date

Harlan
BIOSERVICE
FOR SCIENCE

1.0 Summary

The potential toxicity of **"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"** was assessed in an acute eye irritation/corrosion test on 3 albino rabbits.
In each animal, 0.1 ml of the test article was introduced into the conjunctival sac of the left eye, the untreated right eye served as control. Both eyes were examined at 1, 24, 48, 72 h and once a day up to day 5 after instillation.

The following results were obtained:

- Redness of conjunctivae, mostly evaluated as moderate (grade 2), were seen in all three animals at 1, 24 and 48 h after treatment. In two animals this findings was still apparent 72 h and 4 days after treatment. Chemosis of conjunctivae, evaluated as slight or moderate (grade 1 to 3) was seen in all animals at 1 and 24 h after instillation and was still apparent in one animal at 48 h after instillation. Additional findings were slight to moderate discharge, observed in all animals at 1 h after instillation and in one animal at 24 h, too, and slight or moderate blood vessel injection at the eyeball, observed in two out of the three animals at 24 and 48 h after treatment and in one animal at 72 h, too.

- All findings were fully reversible, no ocular changes were seen at day 5 after instillation.

- No general toxic effects were observed.

- Mean grades were 1.33 or 2.00 for redness of the conjunctivae and 0.33 or 1.00 for chemosis of the conjunctivae.

Assessment

The mean grades of ocular reactions at 24, 48 and 72 h after instillation were lower than the value classified as irritant by the the EEC Directive 2001/59/EEC of 6 August 2001 and the Gefahrstoffverordnung (GefStoffV) of 15 November 1999 (BGBl. I, p. 2233). When administered to the eye, the test article

"DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)"

may be classified as **"non-irritant"**.

FD350の密閉ボトル試験における生分解性の検証

LABOR L+S GMBH, Dr. A. Haener 2005/01/24

Ready biodegradability-Evaluation of the Aerobic Biodegradability in an Aqueous Medium

FD350の生分解性を検証するため、密閉ボトル試験をOECD及びEECガイドラインに準じて実施した結果、酸素消費量に基づいたFD350の350の生分解性は化学的酸素要求量（COD）と比較され28日後に84%と測定された。また、FD350の生分解は14日後に75%に達し、顕著な生分解性は初めの7日間にみられた。安息香酸ナトリウムの生分解性は14日後に71%に達し、溶液とテストコンディションの安定性が示された。以上の結果より、14日で60%を上回る生分解性を示したFD350は易生分解性溶液に分類された。

DÜRR SYSTEM-HYGIENE FD 350
Desinfektionstücher (Wirkstofflösung)

Ready Biodegradability - Evaluation of the Aerobic Biodegradability in an Aqueous Medium:

CLOSED BOTTLE TEST

BMG report no. 157/b-05

January 2005

BMG
Labors: Analytik, Ökotoxikologie, Verfahrenstechnik

BMG ENGINEERING AG
Labors:
Ifangstrasse 11
CH-8952 Schlieren/Zürich
Tel. 044 732 92 92 • Fax 044 730 92 21
labors@bmgeng.ch
www.bmgeng.ch

SWISS TESTING
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S SERVIZIO DI PROVA IN SVIZZERA
SWISS TESTING SERVICE STS-No. 166

PREFACE

General

Location of study	BMG Engineering Ltd., Ifangstrasse 11, CH-8952 Schlieren
Study director	Dr. A. Häner
Technician	Ms. C. Höin
Title	DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) Ready Biodegradability - Evaluation of the aerobic biodegradability in an aqueous medium: Closed Bottle Test
Test substance	DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung)
BMG sample no.	0511045702
BMG report no.	157/b-05
Test system	Low concentration of microorganisms (derived from the secondary effluent of a municipal sewage treatment plant) in an aqueous medium.
Sponsor	Dr. K.-M. Wolf OROCHEMIE, Postfach 16 30, D-70798 Kornwestheim
Incoming orders	5 November 2004
Study timing	Start of the test: 16 December 2004; End of the test: 13 January 2005
Data storage	Raw data and a copy of the final report are stored in the archives of BMG Engineering Ltd. in Schlieren for 5 years.

Analytical chemistry of the test media:

Potentiometric analysis after 7, 14, 21 and 28 days.

DOC determinations at the beginning and at the end of the test.

Guidelines

The study procedure described in this report was based on the recommendations of the following guidelines:

Organisation for Economic Cooperation and Development (OECD):

OECD Guidelines for the Testing of Chemicals, "Ready Biodegradability: Closed Bottle Test", Procedure 301 D, adopted 17 July 1992.

European Economic Community (EEC):

C.4. Determination of "Ready" Biodegradability: Closed Bottle Test (Method C.4-E); Publication No L 383 A/207-211, 29 December 1992.

The test procedure was conducted as described in detail in BMG's Standard Operating Procedure (Standardarbeitsanweisung BMG-1026).

Quality assurance statement

The study described in this report was conducted in accordance with ISO/IEC 17025.

1. SUMMARY

The biodegradability of DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) exposed to microorganisms derived from the secondary effluent of a municipal sewage treatment plant was investigated under aerobic static exposure conditions.

The biodegradability of DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) based on O_2 consumption was calculated to be 84 % after 28 days as compared to the chemical O_2 demand (COD).

The biodegradation of DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) reached 75 % at the end of the 14-d window.

Significant biodegradation of the test substance was observed within the first 7 days.

The procedure control sodium benzoate reached 71 % biodegradation after 14 days, thus confirming suitability of inoculum and test conditions.

DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) reached the pass level of 60 % for ready biodegradability in the Closed Bottle Test within the 14-d window and, therefore, can be termed as readily biodegradable.

2. PURPOSE

The objective of this study was to determine the ready biodegradability of DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) under aerobic static exposure conditions using the Closed Bottle Test.

In this method, a low concentration of bacterial inoculum (10^4-10^6 cells/l) derived from the secondary effluent of a sewage treatment plant, mineral nutrients and the test material as the sole source of organic carbon were incubated together in a closed glass vessel placed in the dark without shaking under controlled conditions.

The degradation of the test material was monitored by potentiometric determinations of the dissolved O_2 in the test vessels. The measurements were taken every 7 days over a period of 28 days.

The amount of O_2 taken up by the microbial population during biodegradation of the test substance (corrected for the value in the blank inoculum control) was expressed as percentage of the theoretical O_2 demand, ThOD (or alternatively of the chemical O_2 demand, COD), and served as the measure for the extent of biodegradation.

6. SIGNATURE

It is certified that the test for ready biodegradability of DÜRR SYSTEM-HYGIENE FD 350 Desinfektionstücher (Wirkstofflösung) was carried out under the study director's supervision using the guidelines and standard operating procedures described in this report and that this report forms a true and accurate record of the procedures performed and of the results obtained.

The study was conducted in accordance with ISO/IEC 17025.

.....
Dr. A. Häner (Study Director)

24 January 2005
.....
Date

FD350の原料適合性試験

Orochemie, Dr. rer. nat. D. Heermann and Dr. rer. nat. K.-M. Wolf 2005/01/27

Expertise on the results of testing the material compatibility of the active substance solution of FD350

FD350の原料適合性を検証するため、プラスチック・アルミニウム合金・スチール・非鉄金属などの異なる材質のハンドピース及び鋭利な器具などに対して以下の試験を実施した。
それぞれの器具を3か月間、約100回に渡ってFD350の入った蓋のあるふるい付きの容器に入れ、対象の器具を10秒間1日に2回浸漬し、その後液から取り出した器具を溶液に触れないようふるいの上に移動させ蓋をして湿室に保管した結果、プラスチック材料にのみ言及する必要のないレベルの変化があった以外、別の材料に変化はみられなかった。

orochemie
Hygiene Präparate GmbH + Co
Forschungs- und Entwicklungs-KG

Max-Planck-Straße 27
Tel.: 07154/13 08-0
D-70806 Kornwestheim

January 27, 2005
HE

DÜRR SYSTEM-HYGIENE
FD 350
Disinfection Wipes

Expertise
on the results of testing the material compatibility of the active substance solution of FD 350

The aim of the test was to determine the material compatibility of the active substance solution of FD 350 with different materials, e.g. handpieces and angular pieces. The test objects were made out of different plastic materials as well as aluminium alloys, steels and non-ferrous metals. The tests were carried out as described in the following:

The testing objects were put into a vat with a sieve, the active substance solution of FD 350 was put into the vat. Then the vat was closed with a lid. The testing objects were dipped into the active substance solution of FD 350 twice a day for 10 seconds. Afterwards, they were taken out of the solution and stored on the sieve of the vat without contact with the solution. The vat was then closed with the lid and stored in the steam room.

This procedure was carried out approx. 100 times. The test period lasted for 3 months.

Result:

No optical changes of the different materials occurred. The reference of the plastic materials can be ignored.

(Dr. rer.nat. D. Heermann)

(Dr. rer.nat. K.-M. Wolf)

GA/gb/27.01.2005

FD350の原料適合性試験

Orochemie, Dr. rer. nat. D. Heermann and Dr. rer. nat. K.-M. Wolf 2005/01/28

Expertise on the results of testing the material compatibility of the active substance solution of FD350

FD350の原料適合性を検証するため、6週間に渡ってSIEMENSデンタルユニットのポリアミド材質部分（PartⅠ,Ⅱ）及びABS樹脂部分（PartⅢ,Ⅳ）に対して本液を約250回スプレーし、払拭せず乾燥させ、スプレーした箇所にはフェルトペンで印を付けて観察をした。試験終了後、不可逆的な色の変化を検出するため部分的にアルコールワイプで払拭した結果、すべての材質においてFD350を使用したことによる不可逆的変化はみられず、プラスチック部分の損傷もなかった。

orochemie
Hygiene Präparate GmbH + Co
Forschungs- und Entwicklungs-KG

Max-Planck-Straße 27
Tel.: 07154/13 08-0
D-70806 Kornwestheim

January 28, 2005
HE

DÜRR SYSTEM-HYGIENE
FD 350
Disinfection Wipes

Expertise
on the results of testing the material compatibility of the active substance solution of FD 350

The aim of the test was to determine the material compatibility of the active substance solution of FD 350 with different materials of the SIEMENS Dental Treatment Units.

For testing, the active substance solution of FD 350 was sprayed on a defined part of the test objects. The sprayed parts were marked by using a felt pen.

The parts I and II consist of polyamide, the parts III and IV of ABS material.

The pieces were sprayed approx. 250 times. The spray disinfectant was not wiped away but was allowed to dry. The tests were carried out over a period of 6 weeks.

After the test, the resulting films were partly wiped away by using an alcoholic solution to enable the detection of irreversible changes in colour.

Result:

None of the 4 materials was irreversibly changed by being sprayed with the active substance solution of FD 350. Furthermore, no damages to the plastic parts could be detected when using FD 350.

(Dr. rer.nat. D. Heermann)

(Dr. rer.nat. K.-M. Wolf)

GA/gb/28.01.2005

DÜRR DENTAL SE（ドイツ）
Höpfigheimer Straße 17
74321 Bietigheim-Bissingen
www.duerr.co.jp

DÜRR DENTAL