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

FD366 sensitive quick-acting surface disinfection
センシティブ｜表面のクイック除菌

2019年2月現在

DÜRR DENTAL

個別診断／試験結果／効能証明書
FD366 sensitive quick-acting surface disinfection
センシティブ｜表面のクイック除菌

FD366センシティブの菌及び真菌（C.アルビカンス）への表面除菌効果検証

PD Dr. med. H.-P. Werner 2008/12/22

Surface Disinfection Wipe disinfection-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、FD366センシティブ（100%濃度/未希釈）は機械的作業で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 UND MIKROBIOLOGIE

Prof. Dr. H.-P. Werner c/o HygCen GmbH 5500 Bischofshofen Austria

orochemie GmbH + Co KG
Max-Planck-Straße 27
D- 70806 Kornwestheim
DEUTSCHLAND

2008-12-22
Prof.We

DÜRR SYSTEM-HYGIENE FD 366 sensitive
Desinfektion alkoholempfindlicher Oberflächen
Surface disinfection
Wipe disinfection - clean conditions

EXPERTISE

Having tested the disinfectant **DÜRR SYSTEM-HYGIENE FD 366 sensitive Desinfektion alkoholempfindlicher Oberflächen** in accordance with the

"Standard methods of the DGHM*) for testing of chemical disinfection methods"
(Status: 2001-09-01)

I hereby issue the following evaluation of the results from the test report of 2008-12-22 (B 15343b):

Results of the in vitro-test

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

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

DÜRR SYSTEM-HYGIENE FD 366 sensitive Desinfektion alkoholempfindlicher Oberflächen results in sufficient reductions (5 lg units of test bacteria S. aureus, E. hirae and P. aeruginosa or 4 lg units of C. ablicans)

under **clean conditions**
as concentrate within 30 seconds.

*) DGHM = German society for Hygiene and Microbiology.

Results obtained in tests simulating conditions in practice

The efficacy of the disinfectant **DÜRR SYSTEM-HYGIENE FD 366 sensitive Desinfektion alkoholempfindlicher Oberflächen** was tested with mechanical action under **clean conditions**.

Under **clean conditions**

the concentrate within 30 seconds

showed sufficient efficacy against the test germs **S. aureus, E. hirae, P. aeruginosa and C. ablicans.**

Application recommendation for DÜRR SYSTEM-HYGIENE FD 366 sensitive Desinfektion alkoholempfindlicher Oberflächen for surface disinfection with mechanical action

According to the results obtained, **DÜRR SYSTEM-HYGIENE FD 366 sensitive Desinfektion alkoholempfindlicher Oberflächen** complies with the

"Requirements Specification for Certification of Chemical Disinfection Processes" by the disinfectant-commission of the VAH*)

under **clean conditions** as

concentrate within 30 seconds.

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

*) VAH= Verbund für angewandte Hygiene

FD366センシティブの菌及び真菌（C.アルビカンス）への表面除菌効果検証

Priv. Doz. Dr. med. Habil. Georg Schrader 2009/01/20

Testing the disinfectant FD366sensitive

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、FD366センシティブ（100%濃度/未希釈）は機械的作業で1分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。

Priv. Doz. Dr. med. habil. Georg Schrader
Facharzt für Hygiene
Thomas-Müntzer-Straße 13, D-99423 Weimar

orochemie GmbH + Co KG

Max-Planck-Straße 27

D- 70806 Kornwestheim

Weimar, 2009-01-20

JUDGEMENT
DÜRR SYSTEM-HYGIENE
FD 366 sensitive
Desinfektion alkoholempfindlicher Oberflächen

After testing the disinfectant **DÜRR SYSTEM-HYGIENE FD 366 sensitive Desinfektion alkoholempfindlicher Oberflächen** according to the „Standard Methods of the DGHM for Testing Chemical Procedures for Disinfection" (status 2001-09-01) - test report 2009-01-20 - I give the following judgement:

In vitro-Tests

The quantitative suspension tests were carried out under clean conditions.

The product **DÜRR SYSTEM-HYGIENE FD 366 sensitive Desinfektion alkoholempfindlicher Oberflächen** showed sufficient reductions (5 lg units of the test bacteria and 4 lg units of C. albicans)

under clean conditions

as a concentrate within 30 seconds.

Tests under practical conditions

The effectiveness of the disinfectant **DÜRR SYSTEM-HYGIENE FD 366 sensitive Desinfektion alkoholempfindlicher Oberflächen** was tested under **clean conditions** with all of the 4 test strains.

Under this conditions shows the

concentrate within 1 minute

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

Application recommendations of DÜRR SYSTEM-HYGIENE FD 366 sensitive Desinfektion alkoholempfindlicher Oberflächen for surface disinfection with mechanical action

According to the results obtained, **DÜRR SYSTEM-HYGIENE FD 366 sensitive Desinfektion alkoholempfindlicher Oberflächen** complies with the „Requirements Specification for the Admission of Chemical Disinfection Processes" in the commission of the VAH

under clean conditions

as a concentrate within 1 minute.

Priv. Doz. Dr. med. habil. Georg Schrader

FD366センシティブの繊細な表面での殺結核菌（マイコバクテリウム）効能検証

HygCen Dr. med. H.-P. Werner and Kathrin Naujox 2009/01/20

FD366sensitive-Disinfection of sensitively surfaces Tuberculocidal activity

FD366センシティブ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・テラエに対して行った結果、20℃の衛生状況下（00.3%アルブミン）において、有効成分1-プロパノール17g／100g及び50%アルキルージメチルーベンジル塩化アンモニウム0.25g／100g　含有のFD366センシティブ（80%濃度/1.25倍希釈）は2分間の作用時間で十分な有効性を示した。

HYGCEN®
Centrum für Hygiene und medizinische Produktsicherheit

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

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-P-715.98.13

orochemie GmbH + Co KG
Max-Planck-Straße 27

D- 78080 Kornwestheim

2009-01-20
Prof. We/ku

DÜRR SYSTEM-HYGIENE
FD 366 sensitive - Desinfektion empfindlicher Oberflächen
Tuberkulozide Wirkung – DIN EN 14348
Phase 2, Stufe 1
DÜRR SYSTEM-HYGIENE
FD 366 sensitive - Disinfection of sensitively surfaces
Tuberculocidal activity – DIN EN 14348
Phase 2, step 1

PRÜFBERICHT/*TESTREPORT*

Proben-Nr. / *Identification of the test laboratory:*	SN 8474
Prüfprodukt / *test product:*	DÜRR SYSTEM-HYGIENE FD 366 sensitive
Chargen-Bez. / *batch no.*:	08337-125　02.12.2008
Auftraggeber / *manufacturer*:	orochemie GmbH + Co KG
Auftragsdatum / *date of order*:	2008-12-02
Materialeingang / *date of delivery*:	2008-12-05
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 100g / *active substances per 100g:*	17g 1-propanol, 0.25g alcyl-benzyl-dimethyl-ammoniumchorid 50%
pH-Werte (DIN EN 19266) / *pH-values (DIN EN 19266)*:	80 % in aqua dest.: 6.79 75 % in aqua dest.: 6.71

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
Geschäftsführerin Dipl.-Ing. (FH) Umwelt- und Hygienetechnik Margrit Werner · Amtsgericht Schwerin HRB 4792 · UST.-Nr.: 178599849

HYGCEN® Centrum für Hygiene und medizinische Produktsicherheit GmbH

Schlussfolgerung / *Conclusion*:

Gemäß DIN EN 14348 (April 2005), weist die Charge 08337-125 - 02.12.2008 des Produktes DÜRR SYSTEM-HYGIENE FD 366 sensitive bei 20 °C unter geringer Belastung nach einer Einwirkzeit von 2 Minuten bei Verdünnung auf 80 % gegen den Referenzstamm *Mycobacterium terrae* eine tuberkulozide Wirkung auf.

According to DIN EN 14348 (April 2005), the batch 08337-125 - 02.12.2008 *of the product* DÜRR SYSTEM-HYGIENE FD 366 sensitive *possesses a tuberculocidal activity for the referenced test strain Mycobacterium terrae under clean conditions (0.03 % bovine albumin) at 20 °C after contact time of 2 minutes when diluted at 80 %.*

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

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

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 exclusively refer to the samples described above. Account of extracts of this test report is only possible by written approval from HygCen.*

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

Kathrin Naujox
Department manager

FD366センシティブのワクシニアウイルス不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 2009/02/23

Effectiveness of FD366 sensitive against vaccinia virus following EN14476 under clean and dirty condition

EN14476に準じて、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衛生状況下及び汚染状況下で15秒・30秒・60秒・120秒・300秒の作用時間にて評価を行った結果、FD366センシティブ（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

28259 Bremen
Norderoog 2

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

23.02.2009
Dr. St/sbe

Mikrolab GmbH Norderoog2 28259 Bremen

orochemie GmbH + Co KG
Postfach 16 30

70798 Kornwestheim

Effectiveness of DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen against vaccinia virus following EN 14476:2007-02 under clean and dirty conditions

EXPERT OPINION

This expert opinion is based on the test report O08ML723V dating 23.02.2009.

Effectiveness of the surface disinfectant DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen of orochemie GmbH + Co KG was investigated against vaccinia virus strain Elstree following EN 14476:2007-02. 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 substance and eight parts by volume of disinfectant. At specified contact times aliquots are taken and residual infectivity is determined.

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 366 *sensitive* Desinfektion empfindlicher Oberflächen was examined undiluted under clean and dirty conditions. 15, 30, 60, 120 and 300 seconds were chosen as exposure times.

DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen reduced the virus titre by ≥ 4 $\log_{10}$-steps after 30 seconds. Therefore, a virucidal activity against vaccinia virus was measured as follows:

undiluted **30 seconds**

Dr. J. Steinmann

FD366センシティブのC型肝炎ウイルス不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 2009/02/06

Efficacy of FD366sensitive against BVDV in a quantitative suspension test at 20℃ following EN14476 under clean and dirty condition

EN14476に準じてFD366センシティブのC型肝炎ウイルス不活性化を検証するため、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20℃の衛生状況下及び汚染状況下で30秒・60秒・120秒の作用時間で評価を行った結果、FD366センシティブ(100%濃度/未希釈)は30秒間の作用時間で衛生状況下及び汚染状況下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

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

06.02.2009
Dr. St/BB

MikroLab GmbH, Norderoog 2, D-28259 Bremen

orochemie GmbH & Co KG
Postfach 16 30

D-70798 Kornwestheim

Efficacy of DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen against BVDV in a quantitative suspension test at 20°C following EN 14476:2007-02 under clean and dirty conditions

EXPERT OPINION

This expert opinion is based on the test report O08ML723B dating 06.02.2009.

The virus-inactivating properties of the surface disinfectant DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen of orochemie GmbH & Co KG against BVDV were investigated by a quantitative suspension test following EN 14476:2007-02 under clean and dirty conditions.

According to this suspension test, a disinfectant or 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 $\log_{10}$ (inactivation ≥ 99.99 %).

DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen was examined undiluted at 20°C. The exposure times were 30, 60 and 120 seconds. After an exposure time of 30 seconds virus reduction exceeded 4 $\log_{10}$-steps. Therefore, a virucidal activity against BVDV was measured as follows:

clean and dirty conditions	**undiluted**	**30 sec**

Dr. J. Steinmann

FD366センシティブのラットへの急性経口毒性試験

HARLAN Bioservice, Dr. G. Arcelin 2009/11/18

Acute Oral Toxicity Study in Rats

OECDの理念に従い、FD366センシティブの急性経口毒性試験を14日間に渡ってラットに対して行った結果、メスのラットへの致死量の平均値は体重に対して2000mg/kg以上であることが実証された。

AMENDED REPORT

DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen

Acute Oral Toxicity Study in Rats

Study Director:	G. Arcelin
Test Facility:	**Harlan Laboratories Ltd.** Wölferstrasse 4 4414 Füllinsdorf / Switzerland
Sponsor:	**orochemie GmbH + Co. KG** Max-Planck-Str.27 70806 Kornwestheim / Germany
Study Identification:	Harlan Laboratories Study **C45094** Harlan CCR Reference 1262701
Version:	Final
Study Completion Date:	18-Nov-2009 (Amended Study Completion Date)

Page 1 of 19

GOOD LABORATORY PRACTICE

STATEMENT OF COMPLIANCE

Harlan Laboratories Study:	C45094
Test Item:	DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen
Study Director:	G. Arcelin
Study Title:	Acute Oral Toxicity Study in Rats

The purity of the test item was not provided and the stability of the test item dilutions under the test conditions is unknown. The formulation trials were performed before the study initiation date. Therefore, they are excluded from this statement.

This study has been performed in compliance with the Swiss Ordinance relating to Good Laboratory Practice, adopted May 18th, 2005 [SR 813.112.1]. This Ordinance is based on the OECD Principles of Good Laboratory Practice, as revised in 1997 and adopted November 26th, 1997 by decision of the OECD Council [C(97)186/Final].

There were no circumstances that may have affected the quality or integrity of the data.

Study Director: G. Arcelin

.....

Date: 18-Nov-2009

This statement was originally signed by the Study director on 09-Sep-2009. This amended report was issued to correct the test item name.

5 CONCLUSION

The median lethal dose of DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen after single oral administration to female rats, observed over a period of 14 days is:

LD_{50} (female rat): greater than 2000 mg/kg body weight

FD366センシティブのラットへの急性経皮毒性試験

HARLAN Bioservice, Dr. G. Arcelin 2009/11/18

Acute Dermal Toxicity Study in Rats

OECDの理念に従い、FD366センシティブの急性経皮毒性試験を14日間に渡ってラットに対して行った結果、オス及びメスのラットへの致死量の平均値は体重に対して2000mg/kg以上であることが実証された。

AMENDED REPORT

harlan™

DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen

Acute Dermal Toxicity Study in Rats

Study Director:	G. Arcelin
Test Facility:	**Harlan Laboratories Ltd.** Wölferstrasse 4 4414 Füllinsdorf / Switzerland
Sponsor:	**orochemie GmbH + Co. KG** Max-Planck-Str.27 70806 Kornwestheim / Germany
Study Identification:	Harlan Laboratories Study **C45105** Harlan CCR Reference 1262702
Version:	Final
Study Completion Date:	18-Nov-2009 (Amended Study Completion Date)

Page 1 of 24

GOOD LABORATORY PRACTICE

STATEMENT OF COMPLIANCE

Harlan Laboratories Study:	C45105
Harlan CCR Reference:	1262702
Test Item:	DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen
Study Director:	G. Arcelin
Study Title:	Acute Dermal Toxicity Study in Rats

The test item purity was not provided and the stability of the test item dilutions under the test conditions is unknown. The formulation trials were performed before the study initiation date. Therefore, they are excluded from this statement.

This study has been performed in compliance with the Swiss Ordinance relating to Good Laboratory Practice, adopted May 18th, 2005 [SR 813.112.1]. This Ordinance is based on the OECD Principles of Good Laboratory Practice, as revised in 1997 and adopted November 26th, 1997 by decision of the OECD Council [C(97)186/Final].

There were no circumstances that may have affected the quality or integrity of the data.

Study Director: G. Arcelin

.....

Date: 18-Nov-2009

This statement was originally signed by the Study Director on 09-Sep-2009. This amended report was issued to correct the test item name.

5 CONCLUSION

The median lethal dose of DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen after single dermal administration to rats of both sexes, observed over a period of 14 days is:

LD_{50} (rat): greater than 2000 mg/kg body weight

FD366センシティブのインビトロ皮膚刺激性試験

HARLAN Bioservice, Dr. Martina Jaeger and Dr. Wolfgang Voelkner 2009/05/29

IN VITRO SKIN IRRITATION TEST: Human skin model test with FD366sensitive

OECDの理念のもと、欧州代替法バリデーションセンター(ECVAM)、ヨーロッパ共同体（EC）及びOECDガイドラインに準じて、FD366センシティブの人体皮膚刺激性を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）、5%ラウリル硫酸ナトリウム（ポジティブコントロール）を各15μm皮膚モデルに塗布し15分間検証を行った。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ではネガティブコントロールと比較して24.7%の吸収率の誘発減少が見られたがこのテスト法の基準内であった。FD366センシティブを塗布後の吸収値は42.1%減少したがこれは刺激性判断基準値の50%以下であったことからFD366センシティブは皮膚刺激の可能性をもつ薬液であると考えられ、皮膚刺激性薬液であることが実証された。

harlan™

STUDY NUMBER 1262703

IN VITRO SKIN IRRITATION TEST:

HUMAN SKIN MODEL TEST

WITH

DÜRR SYSTEM-HYGIENE FD 366 *sensitive*
Desinfektion empfindlicher Oberflächen

REPORT

Study Completion Date: May 29, 2009

2 CONTENTS

3.4 Project Staff Signatures

Study Director Dr. Martina Jäger

M. Jäger

Date: May 29, 2009

Management Dr. Wolfgang Völkner

G. Völkner

Date: May 29, 2009

3.5 Good Laboratory Practice

The study was performed in compliance with:

"Chemikaliengesetz" (Chemicals Act) of the Federal Republic of Germany, "Anhang 1" (Annex 1) dated July 25, 1994 ("BGBl. I 1994", pp. 1703), last revision: June 27, 2002.

"OECD Principles of Good Laboratory Practice", as revised in 1997 [C(97)186/Final].

3.6 Guidelines

The test was performed as described in the following guidelines:

ECVAM international validation study on *in vitro* tests for acute skin irritation: Report on the validity of the EPISKIN and EpiDerm assays and on the Skin Integrity Function Test (Altern Lab Anim. 2007 Dec; 35 (6): 559-601).

European Commission: Institute for Health an Consumer Protection and European Centre for the Validation of Alternative Methods (ECVAM): Statement on the validity of *in-vitro* tests for skin irritation (2007).

OECD Guideline for the Testing of Chemicals, Draft Proposal for a New Guideline, *In Vitro* Skin Irritation: Human Skin Model Test, December 2007.

10 DISCUSSION

This *in vitro* study was performed to assess the irritation potential of DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen by means of the Human Skin Model Test.

Three tissues of the human skin model EPISKIN were treated with either the test item, the negative or the positive control for 15 minutes.

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

15 µL of either the negative control (deionised water) or the positive control (5% Sodium lauryl sulfate) were applied to each tissue.

After treatment with the negative control the absorbance values were well above the required acceptability criterion of mean OD ≥ 0.6 for the 15 minutes treatment interval 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 24.7% thus ensuring the validity of the test system.

After treatment with the test item DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen the relative absorbance values were decreased to 42.1%. This value is below the threshold for irritancy of ≤ 50%. Therefore, the test item is considered to possess an irritant potential.

11 CONCLUSION

In conclusion, it can be stated that in this study and under the experimental conditions reported, the test item DÜRR SYSTEM-HYGIENE FD 366 *sensitive* Desinfektion empfindlicher Oberflächen is **irritant** to skin.

FD366センシティブの牛摘出角膜の混濁及び透過性試験による眼刺激性検証

HARLAN Bioservice, Dipl.-Ing. Andreas Heppenheimer 2012/11/26

BOVINE CORNEAL OPACITY AND PERMEABILITY ASSAY with FD366sensitive

FD366センシティブの角膜刺激性及び損傷の可能性を純水（ネガティブコントロール）、エトキシエタノール（ポジティブコントロール）及び100%濃度／未希釈の本液を使用し、OECD及びEUのテストガイドラインに準じて牛摘出角膜の混濁及び透過性試験法を用いて検証した。その結果、ネガティブコントロールでは検体に混濁も透過性もみられなかったが、ポジティブコントロール下では明らかな角膜の混濁とはっきりとした透過性がみられた為、眼腐食性と深刻な眼刺激があると判断された。一方、FD366センシティブはわずかな角膜混濁を引き起こしたが透過性はみられず、以上の結果よりFD366センシティブはOECD437の判断基準に準じて非腐食／刺激性薬液に分類され、眼刺激性のない薬液であることが実証された。

harlan®

HARLAN CCR STUDY 1516000

BOVINE CORNEAL OPACITY AND PERMEABILITY ASSAY (BCOP)

WITH

Dürr System-Hygiene FD 366 sensitive
Desinfektion empfindlicher Oberflächen

(OTHER NAMES OF THE TEST ITEM: B 45 and ACD 43)

REPORT – 3rd Original of 3 –

Study Completion Date: November 26, 2012

4 PREFACE

4.1 General

Title:	Bovine Corneal Opacity and Permeability Assay (BCOP) with Dürr System-Hygiene FD 366 sensitive Desinfektion empfindlicher Oberflächen (Other names of the test item: B 45 and ACD 43)
Sponsor:	orochemie GmbH + Co. KG Max-Planck-Straße 27 70806 Kornwestheim Germany
Study Monitor:	Dr. Klaus-Michael Wolf
Test Facility:	Harlan Cytotest Cell Research GmbH (Harlan CCR) In den Leppsteinswiesen 19 64380 Rossdorf Germany

4.2 Responsibilities

Study Director:	Dipl.-Ing. Andreas Heppenheimer
Deputy Study Director:	Dr. Martina Jäger
Management:	Dr. Wolfgang Völkner
Head of Quality Assurance Unit:	Frauke Hermann

4.3 Schedule

Experimental Starting Date:	October 25, 2012
Experimental Completion Date:	October 25, 2012

4.4 Project Staff Signature

Study Director Dipl.-Ing. Andreas Heppenheimer

Date: November 26, 2012

4.5 Good Laboratory Practice

The study was performed in compliance with:

"Chemikaliengesetz" (Chemicals Act) of the Federal Republic of Germany, "Anhang 1" (Annex 1), in its currently valid version.

"OECD Principles of Good Laboratory Practice", as revised in 1997 [C(97)186/Final].

4.6 Guidelines

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

Bovine Corneal Opacity and Permeability (BCOP) Assay, SOP of Microbiological Associates Ltd., UK, Procedure Details, April 1997.

OECD Guideline for Testing of Chemicals 437: Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants (September, 2009).

Commission Regulation (EU) No 1152/2010: B. 47. Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants (Official Journal of the European Union, L 324, 9.12.2010).

4.7 Archiving

Harlan CCR will archive:

Raw data, study plan, report, and specimens (if any) for at least 3 years at the test facility's archive. Thereafter, the material will be transferred to the GLP archive of Harlan Laboratories Ltd. in Füllinsdorf, Switzerland for archiving the remaining time up to a total archiving period of 15 years. No data will be discarded without the Sponsor's written consent.

A sample of the test item will be archived two years after the expiration date provided by the Sponsor. If no expiration date is given, the archiving period will be the required 15 years. Thereafter the samples will be discarded without further notice.

4.8 Deviations from the Study Plan

In the present study there were no deviations from the study plan.

13 DISCUSSION

This *in vitro* study was performed to assess the corneal irritation and damage potential of Dürr System-Hygiene FD 366 sensitive Desinfektion empfindlicher Oberflächen by means of the BCOP assay using fresh bovine corneae.

The test item was tested undiluted. The positive control 2-Ethoxyethanol was tested neat. Saline was used as negative control item.

After a first opacity measurement of the fresh bovine corneae (t_0), the neat test item Dürr System-Hygiene FD 366 sensitive Desinfektion empfindlicher Oberflächen, the positive, and the negative controls were applied to corneae and incubated for 10 minutes at 32 ± 1 °C. After the incubation phase the test item, the positive, and the negative controls were each rinsed from the corneae. Further, the corneae were incubated for another 120 minutes at 32 ± 1 °C in complete medium, and opacity was measured a second time (t_{130}).

After the opacity measurements permeability of the corneae was determined by measuring spectrophotometrically the transfer of sodium fluorescein after incubation in a horizontal position for 90 minutes at 32 ± 1 °C.

With the negative control (saline) neither an increase of opacity nor permeability of the corneae could be observed (mean *in vitro* irritation score 1.33).

The positive control (2-Ethoxyethanol) showed clear opacity and distinctive permeability of the corneae (mean *in vitro* irritation score 62.93) corresponding to a classification as corrosive / severe irritant to the eye (CLP/EPA/GHS (Cat 1)).

Relative to the negative control, the test item Dürr System-Hygiene FD 366 sensitive Desinfektion empfindlicher Oberflächen caused a slight increase of the corneal opacity. Permeability effects could not been observed. The calculated mean *in vitro* irritation score was 12.27 (threshold for corrosivity / severe irritancy: ≥ 55.1). According to OECD 437 the test item is classified as not corrosive / not severe irritant to the eye.

14 CONCLUSION

In conclusion, according to the current study and under the experimental conditions reported, the test item Dürr System-Hygiene FD 366 sensitive Desinfektion empfindlicher Oberflächen is not corrosive to the eye (CLP/EPA/GHS (Cat 1)).

FD366センシティブの密閉ボトル試験における生分解性の検証

LABOR L+S GMBH 2010/02

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

FD366センシティブの生分解性を検証するため密閉ボトル試験を実施した結果、酸素消費量に基づいた本液の生分解性は化学的酸素要求量（COD）と比較され、28日後に71%と測定された。また、FD366センシティブの生分解は14日後に73%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10日で60%を上回る生分解性を示したFD366センシティブは易生分解性溶液に分類された。

DÜRR SYSTEM_HYGIENE FD 366 sensitive
Desinfektion empfindlicher Oberflächen

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

CLOSED BOTTLE TEST

BMG report no. A10-00164/c

February 2010

BMG
Labors: Analytik, Ökotoxikologie, Verfahrenstechnik

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

1. SUMMARY

The biodegradability of DÜRR SYSTEM_HYGIENE FD 366 sensitive Desinfektion empfindlicher Oberflächen 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 366 sensitive Desinfektion empfindlicher Oberflächen based on O_2 consumption was calculated to be 71% after 28 days as compared to the chemical O_2 demand (COD).

The biodegradation of DÜRR SYSTEM_HYGIENE FD 366 sensitive Desinfektion empfindlicher Oberflächen reached 63% at the end of the 10-d window.

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

The procedure control sodium benzoate reached 73% biodegradation after 14 days, thus confirming suitability of inoculum and test conditions.

DÜRR SYSTEM_HYGIENE FD 366 sensitive Desinfektion empfindlicher Oberflächen reached the pass level of 60% for ready biodegradability in the Closed Bottle Test within the 10-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 366 sensitive Desinfektion empfindlicher Oberflächen 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.

FD366センシティブの材料適合性検証

Orochemie, Dr. rer. nat. D. Heermann and A. Schneider 2009/02/05

Summary of the internal and external investigations into the material comparibility of FD366sensitive

FD366センシティブの材料適合性を検証するため、既に市場にある2商品と比較試験を行ったところ、長時間本液に暴露した後のひび割れはみられたがその範囲及び程度は他の2商品と比較してはるかに低かった。また、外部の材料適合性試験機関であるEvonikの検証結果からもFD366センシティブはテスト材料の人口皮革に目立った変化（表面のざらつき・本液塗布部位とその他の部位との境界・色の変化）はみられず、材料適合性が実証された。
以上のテスト結果より、FD366センシティブは商品情報にある使用上の注意を守って正しく使用された場合には材料に対する損傷はない薬液であることが証明された。

DESINFEKTION · HYGIENE · FOTOCHEMIE

orochemie

DÜRR SYSTEM-HYGIENE
FD 366 sensitive
Disinfection of sensitive surfaces

05.02.2009
AS

Summary of the internal and external investigations into the material compatibility of FD 366 sensitive

In the course of examining the compatibility with polyacrylate by means of the pin impression method, the product FD 366 sensitive showed far better results than the two products Bacillol 25 supplied by Bode and Esemfix supplied by Schülke & Mayr, which had already been in the market. In the tests made with FD 366 sensitive, stress crackings appeared after a longer exposure time and to a lesser extent compared with tests made with the two competitive products.
The compatibility of the product FD 366 sensitive was confirmed by external tests made by Evonik (formely Röhm, leading manufacturer of polyacrylates ("Plexiglas")), see test protocol No. 08/278 of 15 December 2008.

The product FD 366 sensitive did not produce noticeable changes with regard to the test material consisting of upholstery fabrics (artificial leather). The haptics seemed to be unchanged. There was no phase boundary between the parts of the test strips which had been immersed and those which had not been immersed. The colour did not bleed.

To sum it up it can be said that the product FD 366 is compatible with the reference material chosen for this purpose. On the basis of the results on hand, damages to the material can be excluded if the product is used appropriately in accordance with the instructions given in the product information sheet.

Dr. rer.nat. D. Heermann

A. Schneider

orochemie GmbH + Co KG · Max-Planck-Straße 27 · D-70806 Kornwestheim · Telefon (07154) 1308-0
Telefax (07154) 1308-40 · info@orochemie.de · www.orochemie.de · www.orochemie-private-label.de
Sitz: 70806 Kornwestheim · Amtsgericht Stuttgart HRA 201527 · Persönlich haftende Gesellschaft: orochemie Verwaltungs-GmbH, HRB 200833 · Geschäftsführer: Martin Dürrstein, Christian Pflug · USt-ID: DE 146 146 522 · Steuer-Nr. 71378-20208 Finanzamt Ludwigsburg · BW Bank Stuttgart, Konto-Nr. 2 716 725, BLZ 600 501 01, S.W.I.F.T.-Adresse SOLADEST

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

DÜRR DENTAL