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

Orotol plus® disinfection of suction system

オロトルプラス｜吸引システムの除菌

2019年5月現在

DÜRR DENTAL

個別診断／試験結果／効能証明書
Orotol plus® disinfection of suction system
オロトルプラス｜吸引システムの除菌

オロトルプラスの器具消毒薬としての検証

PD Dr.med.F.-A.Pitten 2008/09/04

Chemical disinfection of instruments used in the medical area

ドイツ応用衛生協会（DGHM）基準に従い本液の器具消毒薬としての菌および真菌への効果を検証した。
菌および真菌への適切な不活性成分の有効性評価を行った結果、各菌および真菌の増殖阻害のため本液の最低希釈濃度は黄色ブドウ球菌（0.01%濃度）、腸内連鎖球菌（0.05%濃度）、腸内細菌および緑膿菌（0.5%濃度）、カンジダ・アルビカンス（0.75%濃度）であった。（本液に含有される中和成分、CSL・3%界面活性剤・3%サポニン・0.1%システイン・ヒスチジンの安全性は確認されている）

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 orotol® PLUS Sauganlagendesinfektion“

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

Graz, January 8th, 2007

定量的浮遊実験を用いた菌および真菌への有効性評価を行った結果、最低作用時間5分間実施した際の本液の希釈濃度は腸内連鎖球菌（0.5%濃度）、黄色ブドウ球菌・腸内細菌・カンジダ・アルビカンス（1.0%濃度）、緑膿菌（1.5%濃度）であった。
定量的浮遊実験を用いた菌および真菌へのより厳しい条件での有効性評価を行った結果、最低作用時間5分後に5log菌が減少した際の本液の希釈濃度は、黄色ブドウ球菌・腸内連鎖球菌（0.5%濃度）、緑膿菌（1.0%濃度）、また4log菌が減少した際の希釈濃度はカンジダ・アルビカンス（1.0%濃度）であった。
菌および真菌へのより厳しい条件での化学的器具消毒評価を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌、カンジダ・アルビカンスを検体とし、磨りガラスをキャリアーとして用いて細菌浸漬試験で行った結果、本液（2.0%濃度/50倍希釈）は5分間の作用時間で十分な有効性を示した。以上の試験評価より、オロトルプラス（2.0%濃度/50倍希釈）は5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。

EVALUATION

General specifications regarding the tested product „DÜRR SYSTEM-HYGIENE orotol® PLUS Sauganlagendesinfektion“
(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% Cysteine + 0,1% Histidin was 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 0,01% for S.aureus, 0,05% for E.faecium, E.coli and E.hirae, 0,5% for P.mirabilis and P.aeruginosa and 0,75% for C.albicans.

2 Evaluation of the bactericidal and fungicidal efficacy in the qualitative suspension test

The minimal 5 minutes contact bactericidal/fungicidal concentration of the tested product was 0,50% for E.hirae and E.coli, 1,00% for S.aureus, P.mirabilis and C.albicans and 1,50% for P.aeruginosa.

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

The required 5 log reduction factor after 5 minutes contact was reached at a product concentration of 0,50% for S.aureus and E.hirae. The factor was 1% for P.aeruginosa. The required 4 log reduction after a 5 minutes contact for C.albicans was reached at a product concentration of 1,50%.

4 Chemical instrument disinfection – practical germ carrier testing Evaluation of the bactericidal and fungicidal efficacy (under high challenge)

Test surface: Frosted glass, 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 an instrument disinfectant in a 2,00% concentration after 5 minutes contact time.

CONCLUSION

According to the requirements (February 4th, 2002) of the German Society for Hygiene and Microbiology for the testing of chemical disinfectants the tested product

„DÜRR SYSTEM-HYGIENE orotol® PLUS Sauganlagendesinfektion"

has been proved to be a suitable preparation as an instrument disinfectant under high challenge for the prophylaxis of nosocomial infections in the hospital and the general practice if used

in a 2,00% concentration after 5 minutes contact

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

オロトルプラスの医療領域における器具化学的消毒薬としての有効性検証

PD Dr.med.F.-A.Pitten 2006/11/03

Chemical disinfection of instruments used in the medical area

DGHMのガイドラインに従い、本液の医療領域における器具化学的消毒薬としての菌および真菌への有効性の検証を高有機負荷下での浮遊試験（0.3%ヒツジ赤血球+0.3%アルブミン）および細菌浸漬試験（0.3%ヒツジ赤血球+0.03%アルブミン）を用いて、黄色ブドウ球菌、腸内連鎖球菌、腸内細菌、緑膿菌、カンジダ・アルビカンスに対して行った結果、オロトルプラスは高有機負荷下において5分間（1.0%濃度/100倍希釈）、および60分間（0.75%濃度/133倍希釈）の作用時間で十分な有効性を示し、以上の試験結果はDGHMの評価基準を満たしていることが実証された。

PD Dr. med. F.-A. Pitten

Siemensstraße 18
35394 Gießen
Tel.: 0641/979050
Fax: 0641/9790534

PD Dr. med. F.-A. Pitten – Siemensstraße 18 - 35394 Gießen

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

D – 70806 Kornwestheim

Our Sign
Dr.Pi/mo

Date
November 3th 2006

Expert Opinion

Of the product:	DÜRR SYSTEM-HYGIENE orotol PLUS Sauganlagendesinfektion
To be intended for:	Chemical disinfection of instruments used in the medical area

The testing of the product was carried out according to the standard methods of the German Society of Hygiene and Microbiology (DGHM) for the efficacy testing of chemical disinfectants dating Sep. 2001 ("Standardmethoden der DGHM zur Prüfung chemischer Desinfektionsverfahren").

The test report dates 2th November 2006. The investigated disinfectant sample was denominated "WF-OP". According to the manufactures the composition of "WF-OP" is identical with the product "DÜRR SYSTEM-HYGIENE orotol PLUS Sauganlagendesinfektion".

The obtained data was evaluated using the requirements for the acception of chemical disinfectants in the list of disinfectants published by the DGHM ("Desinfektionsmittel-Liste der DGHM") dating Feb. 2002.

1. Suspensiontests

Neutralization test (Tab. 1 in the test report dating 2006-11-02)

Test organism	Concentration of the test product (%)	
	Without neutralizer	With optimal neutralizer
S. aureus	0.05	1.0
E. hirae	0.05	>2.0
P. aeruginosa	0.5	>2.0
E. coli	0.05	0.75
P. mirabilis	0.5	2.0
C. albicans	0.05	1.5

The most effective neutralizer was:
3.0 % Tween 80, 3.0 % Saponin, 0.1 % Histidin, 0.1 % Cystein

This neutralizer was applied in all subsequent trials.

Assessment of the bactericidal and levurocidal efficacy in the qualitative suspension test after 60 min. (Tab. 2 in the test report dating 2006-11-02)

Test organism	Concentration of the test product (%)
S. aureus	0.25
E. hirae	0.25
P. aeruginosa	0.5
E. coli	0.05
P. mirabilis	0.5
C. albicans	0.25

Due to the results of the qualitative suspension test ***S. aureus, E. hirae, P. aeruginosa*** **und** ***C. albicans*** are required for the quantitative suspension tests.

Assessment of the bactericidal and levurocidal efficacy in the quantitative suspension test (Tab. 3 –6 in the test report dating 2006-11-02)

Sufficient reductions (> 5 lg for bacteria and > 4 lg for yeasts) of the test organisms were yielded using the following relations of time of action and concentration of the test product with **high organic burden** (0.3% albumin and 0.3 % sheep erythrocytes):

Test organism	**Effective concentration (%) at time of action (min)**			
	5	**15**	**30**	**60**
S. aureus	0.5	0.5	0.5	0.5
E. hirae	0.75	0.5	0.5	0.5
P. aeruginosa	1.0	0.75	0.75	0.75
C. albicans	1.0	1.0	1.0	0.75
All test organisms	**1.0**	**1.0**	**1.0**	**0.75**

2. Quantitative germ carrier tests

Quantitative germ carrier tests (Tab. 7- 14 in the test report dating 2006-11-02)

Sufficient reductions (> 5 lg for bacteria and > 4 lg for yeasts) of the test organisms were yielded using the following relations of time of action and concentration of the test product with **high organic burden** (0.03% albumin and 0.3 % sheep erythrocytes):

Test organism	**Effective concentration (%) at time of action (min)**	
	5	**60**
S. aureus	0.75	0.5
E. hirae	0.75	0.5
P. aeruginosa	0.75	0.5
C. albicans	1.0	0.75
All test organisms	**1.0**	**0.75**

Recommendation for the application as chemical disinfectant for the disinfection of instruments in the medical area

The product meets the standards given by the requirements for the acception of chemical disinfectants in the list of disinfectants published by the DGHM ("Desinfektionsmittel-Liste der DGHM") dating Feb. 2002. A sufficient bactericidal and levurocidal efficacy is achieved using the following relations of time of action and concentration under a high organic burden:

5 min – 1.0 %
60 min – 0.75 %

PD Dr. med. F.-A. Pitten

オロトルプラスの表面域への化学的消毒薬としての有効性検証

Dr. E. Marth 2005/11/02

Investigation and evaluation of surface disinfectants of OROTOL PLUS

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。
菌および真菌への適切な不活性成分の有効性評価を行った結果、各菌および真菌の増殖阻害のため本液の最低希釈濃度は黄色ブドウ球菌（0.01%濃度）、腸内連鎖球菌（0.05%濃度）、腸内細菌および緑膿菌（0.5%濃度）、カンジダ・アルビカンス（0.75%濃度）であった。（本液に含有される中和成分、CSL・3%界面活性剤・3%サポニン・0.1%システイン・ヒスチジンの安全性は確認されている）

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 orotol® PLUS Sauganlagendesinfektion“

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, September 1st, 2001 (DGHM)

Graz, November 2nd 2005

定量的浮遊実験を用いた菌および真菌への有効性評価を行った結果、最低作用時間5分間実施した際の本液の希釈濃度は腸内連鎖球菌（0.5%濃度）、黄色ブドウ球菌・腸内細菌・カンジダ・アルビカンス（1.0%濃度）、緑膿菌（1.5%濃度）であった。
定量的浮遊実験を用いた菌および真菌へのより厳しい条件での有効性評価を行った結果、最低作用時間5分後に5log菌が減少した際の本液の希釈濃度は、黄色ブドウ球菌・腸内連鎖球菌（0.5%濃度）、緑膿菌（1.0%濃度）、また4log菌が減少した際の希釈濃度はカンジダ・アルビカンス（1.0%濃度）であった。
菌および真菌へのより厳しい条件での化学的器具消毒評価を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌、カンジダ・アルビカンスを検体とし、磨りガラスをキャリアーとして用いて細菌浸漬試験で行った結果、本液（2.0%濃度/50倍希釈）は5分間の作用時間で十分な有効性を示した。以上の試験評価より、オロトルプラス（2.0%濃度/50倍希釈）は5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。

EVALUATION

General specifications regarding the tested product „DÜRR SYSTEM-HYGIENE orotol® PLUS Sauganlagendesinfektion“ are listed on 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% Cysteine + 0,1% Histidin was 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 0,01% for S.aureus, 0,05% for E.faecium, E.coli and E.hirae, 0,5% for P.mirabilis and P.aeruginosa and 0,75% for C.albicans.

2 Evaluation of the bactericidal and fungicidal efficacy in the qualitative suspension test

The minimal 5 minutes contact bactericidal/fungicidal concentration of the tested product was 0,50% for E.hirae, 1,00% for S.aureus and E.coli and 1,50% for P.aeruginosa, P.mirabilis and C.albicans respectively.

3 Evaluation of the bactericidal and fungicidal efficacy in the quantitative suspension test (under high protein load)

The required 5 log reduction factor after a 5 minutes contact was obtained at a product concentration of 0,50% for S.aureus and E.hirae. The concentration of the disinfectant was 1% for P.aeruginosa. The required 4 log reduction for C.albicans after 5 minutes contact was obtained at a product concentration of 1,50%.

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

Test surface: glazed tiles, 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 at a concentration of 2,00% and 5 minutes residence time.

CONCLUSION

According to the requirements of the German Society of Hygiene and Microbiology (February 4th, 2002) for the testing of chemical disinfectants the tested product

„DÜRR SYSTEM-HYGIENE orotol® PLUS
Sauganlagendesinfektion"

has proved to be a suitable preparation as a surface disinfectant under high protein load for the prophylaxis of nosocomial infections in the hospital and the general practice, if used

at a concentration of 2,00% and 5 minutes of residence time.

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

オロトルプラスの医療領域表面への化学的消毒薬としての有効性検証

PD Dr. med. F.-A. Pitten 2006/02/09

Chemical disinfection of surface in the medical area

DGHMのガイドラインに従い、本液の医療領域表面への化学的消毒薬としての菌および真菌への有効性の検証を高有機負荷下での浮遊試験（0.3%ヒツジ赤血球+0.3%アルブミン）および細菌浸漬試験（0.3%ヒツジ赤血球+0.03%アルブミン）を用いて、黄色ブドウ球菌、腸内連鎖球菌、腸内細菌、緑膿菌、カンジダ・アルビカンスに対して行った結果、オロトルプラスは高有機負荷下において2%濃度（50倍希釈）で5・15・30・60分間、および1%濃度（100倍希釈）240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DGHMの評価基準を満たしていることが実証された。

PD Dr. med. F.-A. Pitten

Siemensstraße 18
35394 Gießen
Tel.: 0641/979050
Fax: 0641/9790534

PD Dr. med. F.-A. Pitten – Siemensstraße 18 - 35394 Gießen

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

D – 70806 Kornwestheim

Our Sign
Dr.Pi/mo

Date
February 9th 2006

Certificate

Of the product:	DÜRR SYSTEM-HYGIENE orotol PLUS Sauganlagendesinfektion
To be intended for:	Chemical disinfection of surfaces in the medical area

The testing of the product was carried out according to the standard methods of the German Society of Hygiene and Microbiology (DGHM) for the efficacy testing of chemical disinfectants dating Sep. 2001 ("Standardmethoden der DGHM zur Prüfung chemischer Desinfektionsverfahren") to assess the bactericidal and levurocidal efficacy in the presence of a high organic burden.

The test report dates 9th February 2006.

The obtained data was evaluated using the requirements for the acception of chemical disinfectants in the list of disinfectants published by the DGHM ("Desinfektionsmittel-Liste der DGHM") dating Feb. 2002.

GA englisch 060203.doc

Results of the in vitro tests

1. Neutralization test (Tab. 1 in the test report dating 2006-02-09)

Test organism	Concentration of the test product (%)	
	Without neutralizer	With optimal neutralizer
S. aureus	0.05	1.0
E. hirae	0.05	> 2.0
P. aeruginosa	0.5	> 2.0
E. coli	0.05	1.5
P. mirabilis	0.5	> 2.0
C. albicans	0.05	2.0

The most effective neutralizer was:
3.0 % Tween 80, 3.0 % Saponin, 0.1 % Histidin, 0.1 % Cystein

This neutralizer was applied in all subsequent trials.

2. Assessment of the bactericidal and levurocidal efficacy in the qualitative suspension test after 60 min. (Tab. 2 in the test report dating 2006-02-09)

Test organism	Concentration of the test product (%)
S. aureus	0.25
E. hirae	0.25
P. aeruginosa	0.5
E. coli	0.05
P. mirabilis	0.5
C. albicans	0.25

Due to the results of the qualitative suspension test ***S. aureus, E. hirae, P. aeruginosa*** und ***C. albicans*** are required for the quantitative suspension tests.

3. Assessment of the bactericidal and levurocidal efficacy in the quantitative suspension test (Tab. 3 –7 in the test report dating 2006-02-09)

Sufficient reductions (> 5 lg for bacterial and > 4 lg for yeasts, fungi and mycobacteria) of the test organisms were yielded using the following relations of time of action and concentration of the test product with **high organic burden** (0.3% albumin and 0.3% sheep erythrocytes):

Test organism	**Effective concentration (%) at time of action (min)**			
	5	15	30	60
S. aureus	0.5	0.5	0.5	0.5
E. hirae	0.75	0.5	0.5	0.5
P. aeruginosa	1.0	0.75	0.75	0.75
C. albicans	1.0	1.0	1.0	0.75
All test organisms	**1.0**	**1.0**	**1.0**	**0.75**

4. Quantitative germ carrier tests (Tab. 8 - 27 in the test report dating 2006-02-09)

Sufficient reductions (> 5 lg for bacterial and > 4 lg for yeasts, fungi and mycobacteria) of the test organisms were yielded using the following relations of time of action and concentration of the test product with **high organic burden** (0.3% albumin and 0.3% sheep erythrocytes) and **with mechanic**:

Test organism	**Effective concentration (%) at time of action (min)**					
	1	5	15	30	60	240
S. aureus	4.0	2.0	2.0	1.0	1.0	1.0
E. hirae	3.0	2.0	2.0	1.0	1.0	1.0
P. aeruginosa	2.0	2.0	1.0	1.0	1.0	0.5
C. albicans	2.0	2.0	2.0	2.0	2.0	1.0
All test organisms	**4.0**	**2.0**	**2.0**	**2.0**	**2.0**	**1.0**

5. Recommendation for the application as chemical disinfection of surfaces in the medical area

The product "DÜRR SYSTEM-HYGIENE orotol PLUS Sauganlagendesinfektion" meets the standards given by the requirements for the acception of chemical disinfectants in the list of disinfectants published by the DGHM ("Desinfektionsmittel-Liste der DGHM") dating Feb. 2002. A sufficient bactericidal and levurocidal efficacy is achieved using the following relations of time of action and concentration:

With mechanic, high organic burden:

5, 15, 30, 60 min	**-**	**2 %**
240 min	**-**	**1 %**

PD Dr. med. F.-A. Pitten

オロトルプラスの定量的浮遊試験における殺菌性

HygCen Dr. Sorger 2007/06/11

Quantitative suspention test for the evaluation of bactericidal activity in the medical area according to EN13727

オロトルプラスの殺菌および消毒力評価のために、EN13727に準じて医療領域における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水を使用し行った結果、20℃の汚染状況下においてオロトルプラス（1.0%濃度/100倍希釈）は5分間の作用時間で十分な有効性を示した。

Werksgelände 24 · 5500 Bischofshofen · Austria

Akkreditierte Prüfstelle nach ÖNORM EN ISO 17025

GZ. BMWA-92.714/0078-II/12/2006

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

Bischofshofen, 2007-06-11
New issue of test report B 7757ge 2005-03-01

Test report B 7757ge – new issue

DÜRR SYSTEM HYGIENE orotol® PLUS Sauganlagendesinfektion

Quantitative suspension test - bactericidal activity

EN 13727 (Draft for Revision) (September 2004) – phase 2 / step 1

Laboratory identification:	B 7757
Test product:	DÜRR SYSTEM HYGIENE orotol® PLUS Sauganlagendesinfektion
Batch number:	WF-OP 56426
Ordered by:	orochemie Dürr + Pflug GmbH + Co KG
Date of order:	2005-02-07
Arrival of test product:	2004-10-22
Testing period:	2005-02-18 – 2005-02-27
Appearance:	clear, yellow liquid
Smell:	aromatically
Active substances in 100 g:	8,8g Dimethyl-dioctyl-ammoniumchlorid 50% 1,2g Benzyl-dimethyl-dodecyl-ammoniumchlorid 50%
Method:	EN 13727 (Draft for Revision) (September 2004) Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area (phase 2, step 1)

Geschäftsführer: Prof. Dr. H.-P. Werner
HygCen International GmbH
Werksgelände 24
5500 Bischofshofen · Austria

Telefon: +43 (6462) 53 19
Telefax: +43 (6462) 32 753
mobil: +43 (664) 503 85 59
e-mail: office@hygcen.at

Bankverbindung:
Oberbank AG
BLZ: 15092
Kto-Nr.: 141-0319.48

Landesgericht Salzburg
FN 180657 y
UID-Nr.: ATU 46628403

11.06.2007

Conclusions:

According to EN 13727 (Draft for Revision) (September 2004) the batch WF-OP 56426 of the product DÜRR SYSTEM HYGIENE orotol® PLUS Sauganlagendesinfektion possesses a bactericidal activity at 20 °C, under dirty conditions in 5 minutes for the referenced strains *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541 and *Pseudomonas aeruginosa* ATCC 15442 when diluted at 1,0 % (v.v) in water standardized hardness.

The test results in this test report relate only to the items tested. This test report shall not be reproduced except in complete text without the written approval of the testing laboratory.

The test report B7757ge is withdrawn with this new copy. We ask you to forward this new copy to all persons and institutions, who already have received this test report or otherwise we can forward it also. We regret this error and hope it didn't cause any inconveniences. For possible further inquiries – in particular if you already suffered damage threw the incorrect report – please ring our technical manager Dr. Sorger telephone number +43 (664) 503 85 59.

Dr. Sorger
technical manager

as/2007-06-11

HygCen International GmbH Werksgelände 24, 5500 Bischofshofen, Austria Basler Str. 109, D-79639 Grenzach-Wyhlen, Deutschland

オロトルプラスの高有機負荷および低有機負荷環境下での殺菌性検証

Laboratoire BIOTECH-GERMANDE Dr.Lionel Pineau 2002/10/24

Determination of the bactericidal activity of the disinfectant orotol PLUS in accordance with the standard prEN13727

オロトルプラスをEN13727に準じて20℃±1℃の低有機負荷（0.3%アルブミン）および高有機負荷（0.3%アルブミン+0.3%赤血球）環境下で2%濃度に希釈し（50倍希釈）60分間作用させたところ殺菌活性を示した。

Laboratoire BIOTECH-GERMANDE
Hygiene – **F**ormation – **E**valuation
Recherche & **D**eveloppement
Parc Scientifique de Luminy
163 Avenue de Luminy
F-13288 Marseille Cedex 9
Phone: +33 491 828240
Fax: +33 491 828249

24 October 2002

Determination of the bactericidal activity of the disinfectant orotol® PLUS in accordance with the standard prEN 13727
(with both high and low load)

Conclusion:

In accordance with the project of the standard prEN 13727 the disinfectant solution orotol® Plus (internal batch No. C.142.DUR.02.344) shows a bactericidal activity in the presence of interfering reference substances (low load: 0.3% albumine; high load: 3% albumine and 3% erythrocytes) at a concentration of 2% (v/v) during an exposure time of 60 minutes at 20°C ± 1°C.

(Dr Lionel Pineau)
(Head of Laboratory)

(Audrey Ribiollet)
(Investigator)

オロトルプラスの定量的浮遊試験における殺真菌性

HygCen Dr. Sorger 2005/02/24

Quantitative suspention test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area according to DIN EN13624

オロトルプラスの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行った結果、20℃の真菌（カンジダ・アルビカンス）汚染状況下においてオロトルプラス（2.0%濃度/50倍希釈）は5分間の作用時間で十分な有効性を示した。

HygCen GmbH · Werksgelände 24 · 5500 Bischofshofen · Austria

Centrum für Hygiene und medizinische Produktsicherheit GmbH

Akkreditierte Prüfstelle nach ÖNORM EN ISO 17025

GZ. 92714/172-I/12/03

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

Bischofshofen, 2005-02-24

Test report B 7757fe

DÜRR SYSTEM HYGIENE orotol® PLUS Sauganlagendesinfektion

Quantitative suspension test - fungicidal activity

DIN EN 13624 (February 2004) – phase 2 / step 1

Laboratory identification:	B 7757
Test product:	DÜRR SYSTEM HYGIENE orotol® PLUS Sauganlagendesinfektion
Batch number:	WF-OP 56426
Ordered by:	orochemie Dürr + Pflug GmbH + Co KG
Date of order:	2005-02-07
Arrival of test product:	2004-10-22
Testing period:	2005-02-18 – 2005-02-20
Appearance:	clear, yellow liquid
Smell:	aromatically
Active substances in 100 g:	8,8g Dimethyl-dioctyl-ammoniumchlorid 50% 1,2g Benzyl-dimethyl-dodecyl-ammoniumchlorid 50%
Method:	DIN EN 13624 (February 2004) Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area (phase 2 / step 1)

Geschäftsführer: Prof. Dr. H.-P. Werner
HygCen · Centrum für Hygiene und medizinische Produktsicherheit GmbH
Werksgelände 24
5500 Bischofshofen Austria
Telefon: +43 (6462) 53 19
Telefax: +43 (6462) 32 753
mobil: +43 (664) 503 85 59
e-mail: office@hygcen.at
Bankverbindung: Raika Altenmarkt
BLZ: 35004
Kto-Nr.: 00 200 691
Landesgericht Salzburg
FN 180657 y
UID-Nr.: ATU 46628403

2005-02-24

Centrum für Hygiene
und medizinische Produktsicherheit GmbH

Conclusions:

According to DIN EN 13624 (February 2004) the batch Charge WF-OP 56426 of the product DÜRR SYSTEM HYGIENE orotol® PLUS Sauganlagendesinfektion possesses a fungicidal activity at 20 °C, under dirty conditions in 5 minutes for the referenced strain *C. albicans* when diluted at 2,0 % (v.v).

Dr. Sorger
technical manager

as/2005-02-24

HygCen · Centrum für Hygiene und medizinische Produktsicherheit GmbH Werksgelände 24 5500 Bischofshofen Austria

オロトルプラスの殺真菌性検証

Dr.Holger Brill 2006/08/14

Test and evaluation for fungicidal activity according to DIN EN13624

オロトルプラスの殺真菌性をEN13624に準じて、アスペルギウス・ニガーを用いて検証した結果、2.0%濃度（50倍希釈）で30分および60分の作用時間で十分な有効性を示した。

DR. RER. NAT. HOLGER BRILL

C/O DR. BRILL + PARTNER GMBH
LABOR FÜR HYGIENE UND MIKROBIOLOGIE
PAPENREYE 61, 22453 HAMBURG, GERMANY
TELEFON 0049-40/557631-0
TELEFAX 0049-40/557631-11
EMAIL INFO@BRILLHYGIENE.COM
INTERNET WWW.BRILLHYGIENE.COM

DR. H. BRILL · C/O DR. BRILL + PARTNER GMBH · PAPENREYE 61 · 22453 HAMBURG, GERMANY

orochemie Hygiene Präparate GmbH + Co.
Postfach 1630
D – 70798 Kornwestheim
Germany

Hamburg, 14 August 2006

Dürr System Hygiene orotol Plus - disinfection of Suction systems

Expert's report

The disinfectant of Suction systems ***orotol Plus*** was tested and evaluated according to DIN EN 13624:2003.

According to test report no. L 06/042 of Dr. Brill + Partner GmbH, Germany, the test preparation proved to be fungicidal against the test germ *Aspergillus niger.*

orotol Plus meets the requirements of DIN EN 13624:2003 (disinfection of Instruments; Phase 2, Step 1) within the following concentration-time-relations:

2.0 % 30 and 60 minutes.

Dr. Holger Brill

オロトルプラスの希釈中和法を用いた定量的浮遊試験における殺結核菌性

Dr.Holger Brill 2005/09/24

Determination of tuberculocidal effect of orotol PLUS according to EN14348

オロトルプラスの希釈中和法を用いた殺結核菌力評価のために、医療領域における定量的浮遊試験をEN14348に準じてマイコバクテリウムに対して標準硬度の36±1℃の水を用いて本液を、0.5%・1.0%・2.0%・4.0%の4種の濃度にて希釈し60分・120分・240分の作用時間で評価を行った結果、オロトルプラスは結核菌（マイコバクテリウム）汚染状況下（0.3%牛アルブミン）において60分間（2.0%濃度/50倍希釈）、120分間（1.0%濃度/100倍希釈）および240分（0.5%濃度/200倍希釈）の作用時間で十分な有効性を示した。

DR. RER. NAT. HOLGER BRILL

c/o DR. BRILL + PARTNER GMBH
LABOR FÜR HYGIENE UND MIKROBIOLOGIE
PAPENREYE 61, 22453 HAMBURG
TELEFON 0049-40/557631-0
TELEFAX 0049-40/557631-11
EMAIL INFO@BRILLHYGIENE.COM
INTERNET WWW.BRILLHYGIENE.COM

DR. H. BRILL · c/o DR. BRILL + PARTNER GMBH · PAPENREYE 61 · 22453 HAMBURG

Determination of tuberculocidal effect of DÜRR SYSTEM-HYGIENE orotol® PLUS Sauganlagen - Desinfektion according to EN 14348: 2005

a) Identification of test laboratory:

Dr. Brill + Partner GmbH - Laboratory for Hygiene and Microbiology, Papenreye 61, 22453 Hamburg; Dr. Holger Brill, Margret Becker

b) Identification of the sample:

– Name of the product:	DÜRR SYSTEM-HYGIENE orotol® PLUS Sauganlagen-Desinfektion
– Batch number:	56394
– Manufacturer:	orochemie Dürr + Pflug GmbH & Co. KG, Kornwestheim
– Date of supply:	17.08.2004
– Terms of storage:	room temperature and darkness
– Appearance of the product and its dilutions:	clear, yellow solution
– Recommended diluent:	potable drinking water
– pH value, concentrate:	12.10
– pH value, 1 %:	10.41
– pH value, 4 %:	10.81
– Active agents and concentration in 100 g:	8.8 dimethyl-dioctyl-ammonium chloride, 50 % 1.2 benzyl-dimethyl-dodecyl-ammonium chloride, 50 %

c) Test method and its validation:

– Test method :	Quantitative suspension test (phase 2/step 1)
– Method:	Dilution-neutralisation method

– Medium of neutralisation:	30 g/L polysorbate 80; 30 g/L saponine; 1 g/L histidine; 5 g/L sodium thiosulphate in phosphate buffer (TSH-St)

d) Test conditions:

– Period of the testing:	05.09. to 21.09.2005
– Product diluent:	sterile standardised hard water (SHW), 300 mg/kg $CaCO_3$
– Product test concentrations:	0.5; 1.0; 2.0; 4.0 % volume concentration
– Exposure times:	60, 120, 240 minutes
– Test temperature:	20°C ± 1°C
– Organic load, low:	0.3 g/L bovine serum albumine
– Incubation temperature:	36°C ± 1°C
– Identification of the bacteria strains used:	Mycobacterium terrae ATCC 15755

e) Test results

The test results are summarized in the tables 1.

f) Conclusions

In accordance with prEN 14348 (2005), the batch 56394 of the product ***„DÜRR SYSTEM-HYGIENE orotol® PLUS Sauganlagen-Desinfektion"*** shows in a dilution with hard water under low load (3 g/L bovine serum albumine) a tuberculocidal effect with regard to the test germ Mycobacterium terrae. The following concentration-time relationships (RF ≥ 5.0) proved themselves to be sufficiently effective:

2.0 % 60 minutes
1.0 % 120 minutes
0.5 % 240 minutes

g) Hamburg, 24.09.2005, Dr. Holger Brill

オロトルプラスの希釈中和法を用いた定量的浸漬試験における殺菌性

HygCen, Dr.Wilfield Puchert 2009/12/03

Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area

オロトルプラスの殺菌力評価のために、医療領域における定量的浸漬試験をEN14561に準じて黄色ブドウ球菌、腸内連鎖球菌、緑膿菌に対して標準硬度の水を使用し、4.0%・2.0%・1.0%の3種の濃度にて1分・5分・15分・60分の作用時間で評価を行った結果、20℃の黄色ブドウ球菌、腸内連鎖球菌、緑膿菌汚染状況下（0.3%ヒツジ赤血球+0.3%アルブミン）においてオロトルプラスは1分間（2.0%濃度/50倍希釈）および15分間（1.0%濃度/100倍希釈）の作用時間で十分な有効性を示した。

HygCen International GmbH · Werksgelände 24 · A-5500 Bischofshofen

orochemie GmbH + Co. KG

Max-Planck-Straße 27

D- 70806 Kornwestheim

Akkreditierte Prüfstelle nach ÖNORM EN ISO 17025 und Inspektionsstelle nach ÖNORM EN ISO 17020

Bischofshofen, 03.12.2009

Prüfbericht / test report B 15957b

DIN EN 14561 (August 2006) - Bakterizide Wirksamkeit (Phase 2, Stufe 2)

DIN EN 14561 (August 2006) – bactericidal activity (phase 2, step 2)

Hohe Belastung / *dirty conditions*

Labor-Nr. / *Identification of the test laboratory:*	B 15957
Prüfprodukt / *Test product:*	DÜRR SYSTEM-HYGIENE Orotol® Plus Sauganlagendesinfektion
Chargen-Bez. / *Batch number:*	0911201
Hersteller / *Manufacturer:*	orochemie GmbH + Co KG
Auftragsdatum / *Date of order:*	2009-11-09
Materialeingang / *Date of delivery:*	2009-11-11
Wirkstoff(e) laut Herstellerangabe / *Active ingredient(s):*	in 100g: 8,8 g Dimethyl-dioctyl-ammoniumchlorid 50 % 1,2 g Benzyl-dimethyl-dodecyl-ammoniumchlorid 50 %
Aussehen / *Appearance:*	klare gelbe Flüssigkeit / *clear yellow liquid*
Geruch / *Odour:*	produktspezifisch / *product specific*
pH-Werte / *pH-values:*	4,0 % in WSH[1]: 10,19 2,0 % in WSH: 9,87 1,0 % in WSH: 9,13
Neutralisationsmittel / *Neutralizer:*	3,0% Tween 80 + 0,3% Lezithin + 0,1% Histidin + 0,5% Na-Thiosulfat (TLH-Thio) / *3.0% polysorbate 80 + 0.3% lecithine + 0.1% histidine + 0.5% sodium-thiosulphate (TLH-Thio)*

[1] *water of standardised hardness*

Geschäftsführer: Prof. Dr. med. H.-P. Werner
HygCen International GmbH Prüfinstitut: Werksgelände 24 A-5500 Bischofshofen
Telefon: +43 (0)6462 / 53 19 Telefax: +43 (0)6462 / 32 753 e-mail: office@hygcen.info web: www.hygcen.info
Bankverbindung: Oberbank AG BLZ: 15092 Kto-Nr.: 141-0319.48 IBAN: AT 42 15092 00141031948 BIC: OBKLAT2L
Landesgericht Salzburg · FN 180657 y · UID-Nr.: ATU 46628403

Methodik / *Method*:	**EN 14561 (Aug. 2006)** **Quantitativer Keimträgerversuch zur Prüfung der bakteriziden Wirkung für Instrumente im humanmedizinischen Bereich (Phase 2, Stufe 2)** ***EN 14561 (Aug. 2006)*** ***Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area (phase 2, step 2)***
Prüfzeitraum / *period of analysis*:	2009-11-16 to 2009-11-18
Prüftemperatur / *test temperature*:	20 °C ± 1 °C
Prüfkonzentrationen / *product test concentrations:*	4,0%, 2,0%, 1,0% (m/v) end concentrations
Einwirkzeiten / *contact times*:	1, 5, 15 und 60 Minuten / *1, 5, 15 and 60 minutes*
Auszählverfahren / *counting procedure:*	Plattengussverfahren / *pour plate method*
Inkubation / *incubation*:	48 h - 30 °C ± 1 °C
Probenverdünnungsmittel / *diluent used for product test solution*:	Wasser standardisierter Härte / *water of standardised hardness*
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:*	klar / *clear*
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*:	*Staphylococcus aureus* *ATCC 6538* *Enterococcus hirae* *ATCC 10541* *Pseudomonas aeruginosa* *ATCC 15442*

Schlussfolgerung / *Conclusion:*

Gemäß DIN EN 14561 (Aug. 2006) weist die Charge 0911201 des Produktes DÜRR SYSTEM-HYGIENE Orotol® Plus Sauganlagendesinfektion eine bakterizide Wirkung unter Bedingungen hoher Belastung bei 20°C nach 1 Minute bei Verdünnung auf 2,0 % (v/v) sowie nach 15 Minuten bei Verdünnung auf 1,0% (v/v) in Wasser standardisierter Härte gegen die Testkeime *Stapylococcus aureus, Entercoccus hirae* und *Pseudomonas aeruginosa* auf.

Die Kontrolle der Neutralisation (Ko C) mit dem Testkeim *Staphylococcus aureus* ist bei Einsatz von 0,1 ml des unverdünnten Produktes valide, jedoch nicht bei Einsatz von 1,0 ml.

According to DIN EN 14561 (Aug. 2006) the batch 0911201 of the product DÜRR SYSTEM-HYGIENE Orotol® Plus Sauganlagendesinfektion possesses a bactericidal activity at 20°C under dirty conditions (0.3 % albumin + 0.3 % sheep erythrocytes) for the referenced strains Stapylococcus aureus, Entercoccus hirae and Pseudomonas aeruginos in 1 minute when diluted at 2,0% (v/v) and in 15 minutes when diluted at 1,0% (v/v) in water of standardized hardness.

Control of the neutralization (Ko C) with the test strain Staphylococcus aureus is valid with addition of 0,1 ml the undiluted producte, but not with addition of 1,0 ml.

Dr. Wilfried Puchert
Technischer Leiter / *technical* manager

オロトルプラスの希釈中和法を用いた定量的浸漬試験における殺真菌性

HygCen, Dr. Wilfield Puchert 2009/12/03

Quantitative carrier test for the evaluation of fungicidal or yasticidal activity for instruments used in the medical area

オロトルプラスの殺真菌力評価のために、医療領域における定量的浸漬試験をEN14562に準じてカンジダ・アルビカンスに対して標準硬度の水を使用し、4.0%・2.0%・1.0%の3種の濃度にて1分・5分・15分・60分の作用時間で評価を行った結果、20℃のカンジダ・アルビカンス汚染状況下（0.3%ヒツジ赤血球+0.3%アルブミン）においてオロトルプラスは1分間（4.0%濃度/25倍希釈）、5分間（2.0%濃度/50倍希釈）、15分間（1.0%濃度/100倍希釈）の作用時間で十分な有効性を示した。

HygCen International GmbH · Werksgelände 24 · A-5500 Bischofshofen

orochemie GmbH + Co. KG

Max-Planck-Straße 27

D- 70806 Kornwestheim

Akkreditierte Prüfstelle nach ÖNORM EN ISO 17025 und Inspektionsstelle nach ÖNORM EN ISO 17020

Bischofshofen, 03.12.2009

Prüfbericht / test report B 15957c

DIN EN 14562 (August 2006) - Levurozide Wirksamkeit (Phase 2, Stufe 2)

DIN EN 14562 (August 2006) – yeasticidal activity (phase 2, step 2)

Hohe Belastung / *dirty conditions*

Labor-Nr. / *Identification of the test laboratory:*	B 15957
Prüfprodukt / *Test product:*	DÜRR SYSTEM-HYGIENE Orotol® Plus Sauganlagendesinfektion
Chargen-Bez. / *Batch number:*	0911201
Hersteller / *Manufacturer:*	orochemie GmbH + Co KG
Auftragsdatum / *Date of order:*	2009-11-09
Materialeingang / *Date of delivery:*	2009-11-11
Wirkstoff(e) laut Herstellerangabe / *Active ingredient(s):*	in 100g: 8,8 g Dimethyl-dioctyl-ammoniumchlorid 50 % 1,2 g Benzyl-dimethyl-dodecyl-ammoniumchlorid 50 %
Aussehen / *Appearance:*	klare gelbe Flüssigkeit / *clear yellow liquid*
Geruch / *Odour:*	produktspezifisch / *product specific*
pH-Werte / *pH-values:*	4,0 % in WSH[1]: 10,19 2,0 % in WSH: 9,87 1,0 % in WSH: 9,13
Neutralisationsmittel / *Neutralizer:*	3,0% Tween 80 + 0,3% Lezithin + 0,1% Histidin + 0,5% Na-Thiosulfat (TLH-Thio) / *3.0% polysorbate 80 + 0.3% lecithine + 0.1% histidine + 0.5% sodium-thiosulphate (TLH-Thio)*

[1] *water of standardised hardness*

Geschäftsführer: Prof. Dr. med. H.-P. Werner
HygCen International GmbH Prüfinstitut: Werksgelände 24 A-5500 Bischofshofen
Telefon: +43 (0)6462 / 53 19 Telefax: +43 (0)6462 / 32 753 e-mail: office@hygcen.info web: www.hygcen.info
Bankverbindung: Oberbank AG BLZ: 15092 Kto-Nr.: 141-0319.48
IBAN: AT 42 15092 00141031948 BIC: OBKLAT2L
Landesgericht Salzburg · FN 180657 y · UID-Nr.: ATU 46628403

Methodik / *Method*:	**EN 14562 (Aug. 2006)** **Quantitativer Keimträgerversuch zur Prüfung der fungiziden oder levuroziden Wirkung für Instrumente im humanmedizinischen Bereich** **(Phase 2, Stufe 2)** ***EN 14562 (Aug. 2006)*** ***Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area (phase 2, step 2)***
Prüfzeitraum / *period of analysis*:	2009-11-16 to 2009-11-18
Prüftemperatur / *test temperature*:	20 °C ± 1 °C
Prüfkonzentrationen / *product test concentrations:*	4,0%, 2,0%, 1,0% (m/v) end concentrations
Einwirkzeiten / *contact times*:	1, 5, 15 und 60 Minuten / *1, 5, 15 and 60 minutes*
Auszählverfahren / *counting procedure:*	Plattengussverfahren / *pour plate method*
Inkubation / *incubation*:	48 h - 30 °C ± 1 °C
Probenverdünnungsmittel / *diluent used for product test solution*:	Wasser standardisierter Härte / *water of standardised hardness*
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:*	klar / *clear*
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*

Schlussfolgerung / *Conclusion:*

Gemäß DIN EN 14562 (Aug. 2006) weist die Charge 0911201 des Produktes DÜRR SYSTEM-HYGIENE Orotol® Plus Sauganlagendesinfektion eine levurozide Wirkung unter Bedingungen hoher Belastung bei 20°C nach 1 Minute bei Verdünnung auf 4,0% (v/v), nach 5 Minuten bei Verdünnung auf 2,0% (v/v) und nach 15 Minuten bei Verdünnung auf 1,0% (v/v) in Wasser standardisierter Härte gegen den Testkeim *Candida albicans* auf.

According to DIN EN 14562 (Aug. 2006) the batch 0911201 of the product DÜRR SYSTEM-HYGIENE Orotol® Plus Sauganlagendesinfektion possesses a yeasticidal activity at 20°C under dirty conditions (0.3 % albumin + 0.3 % sheep erythrocytes) in 1 minute when diluted at 4.0% (v/v), in 5 minutes when diluted at 2.0% (v/v), and in 15 minutes when diluted at 1.0% (v/v) in water of standardized hardness for the referenced strain Candida albicans.

Dr. Wilfried Puchert
Technischer Leiter / *technical* manager

オロトルプラスの殺真菌性の検証

Dr. Holger Brill 2006/08/14

Test and evaluation of fungicidal activity according to DIN EN14562

EN14562に準じて高有機負荷のアスペルギウス•ニガーを用いて殺真菌性効力の検証を行った結果、オロトルプラスは30分間（3.0%濃度/33倍希釈）および60分間（2.0%濃度/50倍希釈）の作用時間で十分な有効性を示すことが実証された。

DR. RER. NAT. HOLGER BRILL

C/O DR. BRILL + PARTNER GMBH
LABOR FÜR HYGIENE UND MIKROBIOLOGIE
PAPENREYE 61, 22453 HAMBURG, GERMANY
TELEFON 0049-40/557631-0
TELEFAX 0049-40/557631-11
EMAIL INFO@BRILLHYGIENE.COM
INTERNET WWW.BRILLHYGIENE.COM

DR. H. BRILL · C/O DR. BRILL + PARTNER GMBH · PAPENREYE 61 · 22453 HAMBURG, GERMANY

orochemie Hygiene Präparate GmbH + Co.
Postfach 1630
D – 70798 Kornwestheim
Germany

Hamburg, 14 August 2006

Dürr System Hygiene orotol Plus - disinfection of Suction systems

Expert's report

The disinfectant of Suction systems ***orotol Plus*** was tested and evaluated according to DIN EN 14562:2006.

According to test report no. L 06/042.1 of Dr. Brill + Partner GmbH, Germany, the test preparation proved to be fungicidal against the testgerm *Aspergillus niger* with high organic load.

orotol Plus meets the requirements of DIN EN 14562:2006 (disinfection of Instruments; Phase 2, Step 2) within the following concentration-time-relations:

3.0 % 30 minutes
2.0 % 60 minutes.

Brill

Dr. Holger Brill

オロトルプラスの殺結核菌性の検証

Dr. Holger Brill 2006/10/12

Test and evaluation of tuberculocidal effect according to DIN EN14563

EN14563に準じて有機負荷の無い条件下で結核菌（マイコバクテリウム）を用いて殺結核菌性効力の検証を行った結果、オロトルプラスは60分間（2.0%濃度/50倍希釈）および240分間（1.0%濃度/100倍希釈）の作用時間で十分な有効性を示すことが実証された。

DR. RER. NAT. HOLGER BRILL

C/O DR. BRILL + PARTNER GMBH
LABOR FÜR HYGIENE UND MIKROBIOLOGIE
PAPENREYE 61, 22453 HAMBURG, GERMANY
TELEFON 0049-40/557631-0
TELEFAX 0049-40/557631-11
EMAIL INFO@BRILLHYGIENE.COM
INTERNET WWW.BRILLHYGIENE.COM

DR. H. BRILL · C/O DR. BRILL + PARTNER GMBH · PAPENREYE 61 · 22453 HAMBURG, GERMANY

orochemie Hygiene Präparate GmbH + Co.
Postfach 1630
D – 70798 Kornwestheim
Germany

Hamburg, 12 October 2006

Dürr System Hygiene orotol Plus - Disinfection of suction systems

Expert's report

The disinfectant of Suction systems ***orotol Plus*** was tested and evaluated according to DIN EN 14563:2005.

According to test report no. L 06/042.4 of Dr. Brill + Partner GmbH, Germany, the test preparation proved to be fungicidal against the testgerm *Mycobacterium terrae* without organic load.

orotol Plus meets the requirements of DIN EN 14563:2005 (disinfection of Instruments; Phase 2, Step 2) within the following concentration-time-relations:

2.0 % 60 minutes
1.0 % 240 minutes.

Dr. Holger Brill

オロトルプラスの殺菌性の検証

Laboratoire BIOTECH-GERMANDE, Dr. Lionel Pineau 2002/09/26
Determination of the basic bactericidal activity of the desinfectant orotol PLUS in accordance with the standard NF EN1040

EN1040に準じて緑膿菌と黄色ブドウ球菌を用いて殺菌性効力の検証を行った結果、オロトルプラスは60分間（1.0%濃度/100倍希釈）の作用時間で十分な有効性を示すことが実証された。

Laboratoire BIOTECH-GERMANDE
Hygiene – **F**ormation – **E**valuation
Recherche & **D**eveloppement
Parc Scientifique de Luminy
163 Avenue de Luminy – Case 927
F-13288 Marseille Cedex 9
Phone: +33 491 828240
Fax: +33 491 828249

26 September 2002

DÜRR SYSTEM-HYGIENE
OROTOL PLUS
Disinfection of Suction Systems

Determination of the basic bactericidal activity of the disinfectant DÜRR SYSTEM-HYGIENE OROTOL PLUS (DÜRR DENTAL) in accordance with the standard NF EN 1040

Conclusions:

In accordance with EN 1040 (Febrauary 1997) the disinfectant OROTOL PLUS (internal batch No. C.142.DUR.02.344) shows a bactericidal activity against the reference strains Pseudomonas aeruginosa ATCC 15442 and Staphylococcus aureus ATCC 6538 at a concentration of 1% (v/v) and an exposure time of 60 minutes.

To qualify the product as an antiseptic and/or a chemical disinfectant for a certain application, it will be evaluated by means of additional standardized tests corresponding to the intended application.

(Dr. Lionel Pineau)
(Head of Laboratory)

(Audrey Ribiollet)
(Investigator)

オロトルプラスの殺真菌性の検証

Laboratoire BIOTECH-GERMANDE, Dr. Lionel Pineau 2002/09/27
Determination of the basic fungicidal effectiveness of the desinfectant orotol PLUS in accordance with the standard NF EN1275

EN1275に準じてアスペルギウス・ニガーとカンジダ・アルビカンスを用いて殺真菌性の検証を行った結果、オロトルプラスは60分間（2.0%濃度/50倍希釈）の作用時間で十分な有効性を示すことが実証された。

Laboratoire BIOTECH-GERMANDE
Hygiene – **F**ormation – **E**valuation
Recherche & **D**eveloppement
Parc Scientifique de Luminy
163 Avenue de Luminy
F-13288 Marseille Cedex 9
Phone: +33 491 828240
Fax: +33 491 828249

27 September 2002

DÜRR SYSTEM-HYGIENE
OROTOL PLUS
Disinfection of Suction Systems

Determination of the basic fungicidal effectiveness of the disinfectant DÜRR SYSTEM-HYGIENE OROTOL PLUS (DÜRR DENTAL) in accordance with the standard NF EN 1275

Conclusions:

The disinfectant OROTOL PLUS (internal lot No. C142.DUR.02.344) has a fungicidal activity in accordance with the standard EN 1275 (June 1997) at a 2% concentration (v/v) and an exposure time of 60 minutes at 20°C ±1°C if the reference strains Aspergillus niger ATCC 16404 and Candida albicans ATCC 10231 are used.

To qualify the product as an antiseptic and/or a chemical disinfectant for a certain application, it will be evaluated by means of additional standardized tests corresponding to the intended application.

(Dr. Lionel Pineau)
(Head of Laboratory)

(Audrey Ribiollet)
(Investigator)

オロトルプラスのワクシニアウイルス不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 1997/06/16

On the result of testing the virucidal effectiveness of OROTOL PLUS on the Vaccinia-virus

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試験を、2.0%希釈の本液を用いて5分・10分・15分・30分の作用時間で評価を行った結果、オロトルプラスは60分間（2.0%濃度/50倍希釈）の作用時間で十分な有効性を示すことが実証された。

Dr. Jochen Steinmann
Landesuntersuchungsamt für Chemie, Hygiene und Veterinärmedizin
Fachbereich Medizinische Mikrobiologie und Hygiene
State Hygiene Institute, Department for Medical Microbiology

St. Juergen-Strasse
Tel. (0421) 361-6119
D-28205 BREMEN

June 16, 1997
Dr. St/W

DÜRR SYSTEM-HYGIENE
OROTOL® PLUS
Disinfection of Suction Systems

EXPERTISE

on the results of testing the virucidal effectiveness of OROTOL® PLUS on the Vaccinia-virus

The virus-inactivating properties of OROTOL® PLUS against the viral species Vaccinia, parent Elstree, were examined according to the guidelines of the Federal Health Department (BGA) and the German Association for the Control of Viral Diseases (DVV) for testing the effectiveness of chemical disinfectants against viruses.

According to these guidelines, a disinfectant is effective against viruses, if a reduction of the initial infectious titre by 4 log factors (99.99 %) is reached after a certain action time.

OROTOL® PLUS was tested as a 2 % solution. The exposure times were 5, 10, 15 and 30 minutes.

Based on the results obtained by testing OROTOL® PLUS, the following instructions for use are provided in order to achieve a reliable virucidal activity of OROTOL® PLUS against the Vaccinia virus:

Recommended application

Concentration: 2.0 % - Exposure time: 10 minutes

(Dr. J. Steinmann)

オロトルプラスのC型肝炎ウイルス不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 2001/10/09
BVDV efficacy of OROTOL PLUS

オロトルプラスの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2.0%希釈の本液を用いて0.5分・1分・2分・5分の作用時間で評価を行った結果、オロトルプラス(2.0%濃度/50倍希釈)は牛ウイルス性下痢ウイルス（BVDV）に対して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

Direktor am Landesuntersuchungsamt
für Chemie, Hygiene und Veterinärmedizin
Fachbereich Med. Mikrobiologie und Hygiene

D-28205 Bremen
St.-Jürgen-Straße

Tel.: +49 (0)421 361-6119
Fax.: +49 (0)421 361-15666
E-Mail: JSteinmann@lua.bremen.de

2001-10-09
Dr. St/sbe

Orochemie
Postfach 16 30

70798 Kornwestheim

BVDV efficacy of DÜRR SYSTEM-HYGIENE OROTOL® PLUS Sauganlagendesinfektion

EXPERT'S INVESTIGATION REPORT

The virucidal efficacy of the disinfectant for suction apparates DÜRR SYSTEM-HYGIENE OROTOL® PLUS Sauganlagendesinfektion from the firm Orochemie against bovine viral diarrhea virus (BVDV) was investigated by a quantitative suspension test according to the guideline of the Bundesgesundheitsamt (BGA, Federal Board of Health) and the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (DVV, German Society for the Control of Virus Diseases). BVDV was chosen as a surrogate virus for hepatitis C virus 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 OROTOL® PLUS Sauganlagendesinfektion was examined as a 2.0% solution. The exposure times were 0.5, 1.0, 2.0 and 5.0 minutes. Summarizing the results of the experiments it can be recommended to use the disinfectant for suction apparates DÜRR SYSTEM-HYGIENE OROTOL® PLUS Sauganlagendesinfektion for the inactivation of BVDV as follows:

2.0 % **30 seconds**

Dr. J. Steinmann

オロトルプラスの単純ヘルペスウイルスⅠ型不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 2006/08/18

Herpes simplex Virus type1 efficacy of Orotol Plus in a carrier suspension test at 20℃

オロトルプラスの単純ヘルペスウイルス(HSV)1型不活性化を検証するため、ASTM E2197に準じて定量的浸漬試験を、20℃の環境下でHSV（5.0%牛胎児血清を培地負荷として配合）に対して2.0%希釈の本液を用いて5分・15分・60分の作用時間で評価を行った結果、オロトルプラス(2.0%濃度/50倍希釈)はHSV-1に対して5分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

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

2006-08-18
Dr. St/BB

MikroLab GmbH, Norderoog 2, D-28259 Bremen

orochemie
Postfach 16 30

70798 Kornwestheim

Herpes simplex Virus type 1 efficacy of Dürr System-Hygiene Orotol Plus Disinfection of Suction Systems in a carrier suspension test at 20°C

EXPERT OPINION

The virus-inactivating properties of the Dürr System-Hygiene Orotol Plus Disinfection of Suction Systems of orochemie against Herpes simplex Virus type 1 (HSV) were investigated by a quantitative carrier test according ASTM E 2197 – 02.

In this test a HSV suspension is dried on stainless steel disks followed by the addition of the disinfectant. Finally, recovery of residual infectivity is determined by elution in Earle's balanced salt solution. 5.0% fetal calf serum was incorporated as soil load (Therapeutic Goods Order 54A).

Dürr System-Hygiene Orotol Plus Disinfection of Suction Systems was examined as 2.0% solution at 20°C. Exposure times were 5, 15 and 60 minutes. After an exposure time of five minutes no HSV could be detected on the stainless steel disks. Therefore, a virucidal activity was measured as follows:

2.0% **5 min**

Dr. J. Steinmann

オロトルプラスのアデノウイルス不活性化効力の検証

MikroLab GmbH, Dr.Jochen Steinmann 1996/09/17
On the result of testing the virucidal effectiveness of OROTOL PLUS on the viral species Adeno Types 2, parent Adenoid 6

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、アデノウイルス不活性化効力の試験を行った結果、オロトルプラス(2.0%濃度/50倍希釈)はアデノウイルス2型に対して30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。性を保有することが証明されます。

Dr. Jochen Steinmann
Landesuntersuchungsamt für Chemie, Hygiene und Veterinärmedizin
Fachbereich Medizinische Mikrobiologie und Hygiene
State Hygiene Institute, Department for Medical Microbiology

St. Juergen-Strasse
Tel. (0421) 361-6119
D-28205 BREMEN

September 17, 1996
Dr. St/W

DÜRR SYSTEM-HYGIENE
OROTOL® PLUS
Disinfection of Suction Systems

EXPERTISE

on the results of testing the virucidal effectiveness of OROTOL® PLUS on the viral species Adeno Type 2, parent Adenoid 6

The virus-inactivating properties of OROTOL® PLUS against the viral species Adeno Type 2, parent Adenoid 6, were examined according to the guidelines of the Federal Health Department (BGA) and the German Association for the Control of Viral Diseases (DVV) for testing the effectiveness of chemical disinfectants against viruses.

According to these guidelines, a disinfectant is effective against viruses, if a reduction of the initial infectious titre by 4 log factors (99.99 %) is reached after a certain action time.

Based on the results obtained by testing OROTOL® PLUS as 2.0 % solution, the following instructions for use are provided in order to achieve a reliable virucidal activity of OROTOL® PLUS against the Adeno Virus Type 2:

Recommended application

Concentration: 2.0 % - Exposure time: 30 minutes

(Dr. J. Steinmann)

オロトルプラスのノロウイルス不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 2008/04/15

Efficacy of OROTOL PLUS against FCV in a quantitative suspension test at 20℃ following EN14476:2007-02

オロトルプラス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代用ウイルスのネコカリシウイルス(FCV)に対して本液を1.0%・2.0%・4.0%の濃度に希釈し20℃の清浄および汚染状況下で5分・10分・15分・30分・60分の作用時間で評価を行った結果、オロトルプラス（2.0%濃度/50倍希釈）はネコカリシウイルス(FCV)に対して15分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ノロ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

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

15.04.2008
Dr. St/BB

MikroLab GmbH, Norderoog 2, D-28259 Bremen

orochemie
Dürr + Pflug GmbH + Co KG
Postfach 16 30
D-70798 Kornwestheim

Efficacy of DÜRR SYSTEM-HYGIENE OROTOL PLUS Sauganlagendesinfektion against FCV in a quantitative suspension test at 20°C following EN 14476:2007-02

EXPERT OPINION

This expert opinion is based on the test report O08ML565F.

The virus-inactivating properties of the disinfectant DÜRR SYSTEM-HYGIENE OROTOL PLUS Sauganlagendesinfektion of orochemie against bovine feline Calicivirus (FCV) were investigated by a quantitative suspension test following EN 14476:2007-02 under clean and dirty conditions.

The FCV 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 noroviruses by the disinfectant.

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 OROTOL PLUS Sauganlagendesinfektion was examined as 1.0 %, 2.0 %, and 4.0 % solutions at 20°C under clean and dirty conditions. The exposure times were 5, 10, 15, 30, and 60 minutes. After an exposure time of 15 min (2.0 %) virus reduction exceeded 4 $\log_{10}$-steps. Therefore, a virucidal activity against FCV as surrogate for norovirus was measured as follows:

2.0 % 15 min

Dr. J. Steinmann

オロトルプラスのバクテリアファージMS2不活性化効力の検証

MIDAC Laboratoire, M. Maingain and M. Ch. Lepage 1997/10/27

Determination of the virucidal activity if OROTOL PLUS NEW

本液のバクテリアファージMS2に対する不活性化効力を妥当性確認試験で検証した結果、オロトルプラス（2.0%濃度/50倍希釈）はフランスの標準規格NF T72181に準じた殺ウイルス活性を示すことが実証された

MIDAC LABORATOIRE

Etude, Conseil, Expertise et Formation en Microbiologie.

Test report **n ° 97 358 181-2.**

Laboratoire accrédité par le COFRAC section ESSAIS sous le n° 1 - 0019

On request of : DÜRR DENTAL FRANCE.
11, rue de Miromesnil
75 008 PARIS.

Object : Determination of the virucidal activity of
OROTOL PLUS NEW.
(your ref. : fax of 1997.10.06)

Copy of this test report is only authorized from photographic facsimile of the unabridged version.

It is composed of 3 pages and 0 annex.

229 rue Solférino 59000 LILLE-FRANCE · Tél. 03.20.60.07 09 · Télécopie 03 20.95.90.09

capital de 250.000F · R.C.S. Lille B 329 303 242

TEST RESULTS:

Validation tests : Neutralization by 1/50 dilution in LPT medium.

Tested concentrations in % (v/v) :	Strain :	N	N'	n	T	$\frac{N'}{N}$	$\frac{n}{N}$	$\frac{T}{N'}$
5,0	MS2	393,0	317,0	288,0	241,0	0,80	0,73	0,76

Experimental conditions are validated : N'/N ≥0,5, n/N ≥ 0,5 and T/N' ≥ 0,5.

Actual test.

Strain :	Initial population PFU/ml :	x Concentrations in % (v/v) in contact with the virus :					pH conc.	
		0,5	1,0	2,0	3,0	5,0	mini	maxi
MS 2	$3,54 \times 10^8$	CL	CL	28750	<500	< 500	8,6	10,3

CL : Confluente lysis.

CONCLUSION :

Under the specified conditions and for the sample of product under test, the **OROTOL PLUS NEW (97.05.02 sample) presents a virucidal activity** in accordance with the french standart **NF T72 181**, at the concentration of **2% (v/v)** when the reference strain is **bacteriophage MS2**.

Lille, 27th of October 1997.

Le chef de laboratoire :

Mme. M. MAINGAIN.

Le directeur général :

M. Ch. LEPAGE.

オロトルプラスのラットへの急性経口毒性試験

TOXLABS Prueflabor GmbH, Mr. W. Mueller 1997/06/03
Evaluation of Acute Oral Toxicity with OROTOL PLUS in Rats

オロトルプラスの急性経口毒性試験をウィスターラット（オスおよびメス）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、1993年2月27日付の評議会指令93/21EECのアネックスIVの基準に準じ、本液は人体に有毒または有害ではないと証明された。

***ToxLabs*® Prüflabor GmbH**
Salegaster Chaussee 3
D - 06803 Greppin

Final Report

Evaluation of Acute Oral Toxicity with
DÜRR SYSTEM-HYGIENE
OROTOL® PLUS
Disinfection of suction systems
in Rats

Study No.: *ToxLabs*®/1997/6638 R

June, 1997

Sponsor: OROCHEMIE
Hygiene Präparate GmbH + Co
Forschungs und Entwicklungs KG
Enzstraße 20
D-70806 Kornwestheim

2212609/a PS

Summary

Acute oral toxicity of **DÜRR SYSTEM-HYGIENE, OROTOL®PLUS, Disinfection of suction systems** was tested in female and male Charles River Wistar rats. The test substance was administered in dose of 2000 mg/kg body weight by stomach tube.
Animals were examined for clinical signs, mortality, body weight gain and pathological alterations of organs at the end of 14 days long observation period.

A mortality did not occur.
The LD_{50} p.o. rat is > 2000 mg/kg b.w.

Substance dependent clinical signs, except for a shortly slight squatting position on day of application, pathological findings and an effect to the body weight gain were not observed.

In compliance with the criteria of Annex IV of Council Directive 93/21/EEC Commission Directive of 27th April 1993 **DÜRR SYSTEM-HYGIENE, OROTOL®PLUS, Disinfection of suction systems** is **neither a toxic nor a harmful** substance.

Statement of study director

I herewith declare, that to the best of my knowledge and belief, this study:

Evaluation of Acute Oral Toxicity
with

DÜRR SYSTEM-HYGIENE
OROTOL®PLUS
Disinfection of suction systems

in Rats

made under study No.: *ToxLabs*®/1997/6638 R,

was conducted in compliance with

- the Principles of GLP, Annex 1 of § 19a of Chemicals Act of the Federal Republic of Germany, March 14, 1990 in wording of July 25, 1994.
- the Standard Operating Procedures of the test facility.

There were no unexpected circumstances, which might have affected the quality and integrity of the present study.

June 03, 1997
Date

W. Müller
Study director

オロトルプラスのラットへの急性経皮毒性試験

IWT, W. Mueller 1996/11/25

Evaluation of Acute Dermal Toxicity with OROTOL PLUS in Rats

オロトルプラスの急性経皮毒性試験をウィスターラット（5匹のオスまたはメス）に対し、各ラットの体重に応じて本液2000mg／Kgを、剃毛した背部に塗布し密封包帯で覆った状態で24時間暴露した後、塗布部分を水洗しチェックした。35日間の観察期間後に死亡率、臨床的兆候、適用部位の変化、体重増加および器官の病理学的変化に関して検査した結果、ラットの死亡および臨床的兆候は確認されなかったが、適用部位に緩徐回復性の深度皮膚病変がみられた。また一過性の体重増加はメスにおいてのみみられ、内臓病理学的所見は認められなかった。以上の結果より、1993年4月付の評議会指令93/21EECのアネックスIVの基準に準じ、オロトルプラスの人体皮膚への接触は無害そして無毒であることが証明された。

INGENIEURGESELLSCHAFT
WASSER- UND TIEFBAU mbH

Beratung
Planung
Bauleitung

Ingenieurgesellschaft Wasser- und Tiefbau mbH · Postfach 1159 · 06734 Bitterfeld

Geschäftsbereich
Ökologie + Umweltberatung Bitterfeld

Postfach 1159
06734 Bitterfeld

Zörbiger Straße, Geb. 9.62.0
06749 Bitterfeld

Telefon (0 34 93) 7 24 60
Telefax (0 34 93) 7 33 59

Ansprechpartner/Direktwahl

Unser Zeichen

Datum
November 25, 1996

Final Report

Evaluation of Acute Dermal Toxicity
with

DÜRR SYSTEM-HYGIENE
OROTOL® PLUS
Disinfection of suction systems

in Rats

Study No.: TOX/1996/6638 D

Sponsor: OROCHEMIE
Hygiene Präparate GmbH + Co
Forschungs und Entwicklungs KG
Enzstraße 20
D-70806 Kornwestheim

Summary

Acute dermal toxicity of **OROTOL® PLUS** was tested in each five female and male Charles River Wistar rats. The test substance was applied in a single dose of **2000 mg/kg** body weight to a shaved dorsal area of trunk of the animals and covered with a gauze patch which hold in contact with the skin by an occlusive dressing. Exposure duration was 24 hours. Thereafter the application area was washed using water.

Animals were examined for mortality, clinical signs, alterations at the application area, body weight gain and pathological alterations of organs at the end of 35 days long observation period.

No animal died in the course of testing.
Clinical signs were not observed.
The test substance caused deep skin lesions at the application area, which healed only slowly.
The body weight gain was transient influenced only in the female animals.
There were no pathological findings in the inner organs.

In compliance with the criteria of Annex IV of Council Directive 93/21/EEC Commission Directive of 27th April 1993 **OROTOL® PLUS** is **non toxic** and **non harmful** after dermal application.

Statement of study director

This study:

Evaluation of Acute Dermal Toxicity
with

OROTOL® PLUS

in Rats

made under study No.: TOX/1996/6638 D,

was performed in compliance with

- the Principles of GLP, Annex 1 of § 19a of Chemicals Act of the Federal Republic of Germany, March 14, 1990 in wording of July 25, 1994.

- OECD GUIDELINES FOR TESTING OF CHEMICALS
  Acute Dermal Toxicity
  OECD N° 402
  Adopted by the Council on 24th Feb. 1987

- Appendix IV to Directive 93/21/EEC of the commission of April 27, 1993, relating to the eighteenth adjustment of the Directive 67/548/EEC of the Council for the adaptation to technical progress of legal and administrative regulations for the classification, packaging and designation of hazardous materials.
  Amtsblatt der Europäischen Gemeinschaften L 110 A, 1993

- the Standard Operating Procedures of the test facility.

25-11-96
Date

W. Müller
Study director

オロトルプラスのウサギへの急性眼刺激／腐食性試験

IWT, W. Mueller 1996/10/02

Evaluation of Acute Eye Irritation/Corrosion with OROTOL PLUS in albino rabbits

オロトルプラスの急性眼刺激／腐食性試験を3匹のアルビノウサギに対して行い、本液（2.0%濃度/50倍希釈）を0.1ml片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。24時間後に水洗し、ウサギの臨床的兆候と結膜・角膜・黒目の眼病変を皮膚感作性試験のガイドラインに従い点眼後60分・24時間・48時間・72時間後に検査した結果、点眼1時間後にすべてのウサギの結膜にわずかな発赤がみられ、1匹のウサギの眼には24時間、残りの2匹は48時間この発赤が続いた。
また点眼1時間後に一匹のウサギの角膜にのみわずかな不透明さがみられたが、黒目への影響および全身への毒性はすべてのウサギに現れず、72時間経過後の刺激の兆候も3匹とも見受けられなかった。
以上の結果より、1993年4月27日の評議会指令93/21EEC委員会の付属書（ANNEX IV）に従い、オロトルプラスの2%溶液（50倍希釈）は目に刺激のない物質と証明された。

IWT INGENIEURGESELLSCHAFT WASSER- UND TIEFBAU mbH

Beratung
Planung
Bauleitung

Ingenieurgesellschaft Wasser- und Tiefbau mbH · Postfach 1159 · 06734 Bitterfeld

Geschäftsbereich
Ökologie + Umweltberatung Bitterfeld

Postfach 1159
06734 Bitterfeld

Zörbiger Straße, Geb. 9.62.0
06749 Bitterfeld

Telefon (0 34 93) 7 24 60
Telefax (0 34 93) 7 33 59

Ansprechpartner/Direktwahl

Unser Zeichen

Datum
October 02, 1996

Final Report

Evaluation of Acute Eye Irritation/Corrosion with

DÜRR SYSTEM-HYGIENE
OROTOL® PLUS
Disinfection of suction systems
2 % working solution

in albino rabbits

Study No.: TOX/1996/6640 SR

Sponsor: OROCHEMIE
Hygiene Präparate GmbH + Co
Forschungs und Entwicklungs KG
Enzstraße 20
D-70806 Kornwestheim

Geschäftsführer:
Dipl.-Ing. Dieter Krüger
Dipl.-Ing. Klaus Jähnig

Hauptsitz:
Rießnerstraße 20, 99427 Weimar
Telefon (0 36 43) 43 85 17
Telefax (0 36 43) 43 85 20

Kreisgericht Erfurt,
Kammer für Handelssachen Nr. 756
Ein Unternehmen der EWI-Gruppe

Bankverbindung:
Dresdner Bank Weimar,
BLZ 820 800 00, Kto. 0930 023 500

Summary

The acute eye irritation/corrosion of **OROTOL® PLUS, 2% working solution** was tested in three albino rabbits. The substance was applied in a single dose of 0.1 ml to one of the eyes in each of several animals. The untreated eye was used to provide control information. The eyes were washed out 24 hours after instillation of the test substance.
The animals were examined for clinical signs and the eyes were examined for lesions of conjunctivae, cornea and iris 60 minutes, 24, 48 and 72 hours after application of the test substance. The grades for ocular lesions were recorded in accordance with OECD Guideline 405.

One hour after instillation a slight redness of the conjunctivae was observed in all 3 animals. This slight redness was observed for 24 hours in one and for 48 hours in two animals. A slight chemosis was observed only one hour after instillation in two animals.
The cornea showed a slight opacity one hour after instillation only in one animal.
The iris was not affected.
No systemic toxic effects were observed.

All animals were free of irritation signs 72 hours after application.

In compliance with the criteria of Annex IV of Council Directive 93/21/E.E.C. Commission Directive of 27th April 1993 **OROTOL® PLUS, 2% working solution** is a **non eye irritant** substance.

Statement of study director

This study:

Evaluation of Acute Eye Irritation/Corrosion with

OROTOL® PLUS

2% working solution

in albino rabbits

made under study No.: TOX/1996/6640 SR,

was performed in compliance with

- the Principles of GLP, Annex 1 of § 19a of Chemicals Act of the Federal Republic of Germany, March 14, 1990 in wording of July 25, 1994.

- OECD GUIDELINES FOR TESTING OF CHEMICALS
  Acute Eye Irritation/Corrosion
  OECD N° 405
  Adopted by the Council on 24th Feb 1987

- Appendix IV to Directive 93/21/EEC of the commission of April 27, 1993, relating to the eighteenth adjustment of the Directive 67/548/EEC of the Council for the adaptation to technical progress of legal and administrative regulations for the classification, packaging and designation of hazardous materials.
  Amtsblatt der Europäischen Gemeinschaften L 110 A, 1993

- the Standard Operating Procedures of the test facility.

02-10-96
Date

W. Müller
Study director

オロトルプラスのモルモットへの皮膚感作性試験

HARLAN Bioservice, Dr. A. Marburger and K.-J. Kuehne 2006/10/23
Maximisation Sensitisation Test in the Guinea Pig

モルモットを用いた皮膚感作試験法（GPMT）を使用し、オロトルプラスの皮膚感作性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ず、一般的な毒性影響も確認さ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2004年12月23日のGefahrstoffverordung（GefStofV)によって非皮膚感作薬液であると証明された。

Harlan
BIOSERVICE
FOR SCIENCE

Final Report

Dürr System-Hygiene orotol® Plus
Sauganlagen Desinfektion:
Maximisation Sensitisation Test in the Guinea Pig

Study No.:	**10-5-0155/01-06**
Sponsor:	**orochemie Dürr + Pflug GmbH + Co KG** **Postfach 16 30** **70798 Kornwestheim** **Germany**

Harlan BIOSERVICE FOR SCIENCE

Study Schedule

Experimental Starting Date: 15 August 2006

Experimental Completion Date: 18 September 2006

Study Completion Date: 23 October 2006

Declaration

We, the undersigned, hereby declare that the work performed under our supervision was conducted in accordance with the described procedures. It is assured that the reported results faithfully reproduce the raw data obtained during the experimental work. To the best of our knowledge, no circumstances have been left unreported which may have affected the quality or integrity of the data or which might have a potential bearing on the validity and reproducibility of this study.

The study director accepts overall responsibility for the technical conduct of the study as well as for the interpretation, analysis, documentation and reporting of the results.

A. Marburger — 23-OCT-2006

Dr. A. Marburger
Study Director

Date

K.-J. Kühne — 23.OCT-2006

K.-J. Kühne
Responsible Technician

Date

Harlan BIOSERVICE FOR SCIENCE

1 Summary

The potential skin sensitising properties of the test article "Dürr System-Hygiene orotol® Plus Sauganlagen Desinfektion" 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.

Two weeks following the induction exposure to the test article or the vehicle, animals of both groups were subjected to a challenge exposure with the test article as well as the control article/vehicle.

Due to the strong alkalinity of the test article, the contact sensitising potential of the test article was assessed for a formulation at the concentration of 2% of the provided concentrate. This concentration corresponds to the intended working concentration.

Responses to the challenge procedure were evaluated 24 and 48 h after the end of the exposure period.

The following results were obtained:

- 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%).
- No general toxic effects were seen.

Assessment

According to the EEC Directive 2001/59/EEC, 6 August 2001 and the Gefahrstoffverordnung (GefStoffV) of 23 December 2004 (BGBl. I, p. 3855), the test article

"Dürr System-Hygiene orotol® Plus Sauganlagen Desinfektion"

at the intended working concentration (i.e. a 2% dilution of the supplied concentrate) can be classified as a **"non-sensitiser"** since no allergic responses were observed in the test animals under the experimental conditions of this study.

オロトルプラスの密閉ボトル試験における生分解性の検証

LABOR L+S GMBH, Dr. B. Sonnenschein 1994/03/26

Test report concerning the biodegradability of the OROTOL PLUS in the closed bottle test

オロトルプラスの生分解性を検証するため、密閉ボトル試験をECガイドライン301Dに準じて実施した結果、最終的な生分解性は化学的酸素要求量の79%の生物化学的酸素要求量であり、これらの試験条件下でオロトルプラスは容易生分解性に分類された。

LABOR L + S GmbH
Gesellschaft für Mikrobiologie und biologische Qualitätsprüfung
Laboratories for Microbiological Quality Examination

Mangelsfeld 4
Tel.: (09708) 8 4 8
D-97708 Bad Bocklet

March 26, 1994

No. 11471636

TEST REPORT CONCERNING THE BIODEGRADABILITY OF THE DÜRR SYSTEM-HYGIENE OROTOL® PLUS DISINFECTION OF SUCTION SYSTEMS IN THE CLOSED BOTTLE TEST

Review:

The total decomposition of the test substance after 28 days is 79 % BOD of the COD. The test substance „DÜRR SYSTEM-HYGIENE OROTOL® PLUS Disinfection for Suction Systems" has to be classified as **„easily biodegradable"**.

Summary:

The required liability of the test method is verified by the following process controls. After 28 days the test substance **sodium acetate** shows a degradability of 73 % biological oxygen demand (BOD) of the theoretical oxygen demand (ThOD), the inoculum blind value was < 1,5 mg per litre of the oxygen demand. An inhibiting effect of the test substance on the Inokulum was not provable.

The biodegradability of the test substance „DÜRR SYSTEM-HYGIENE OROTOL® PLUS Disinfection of Suction Systems" was examinated in accordance with the EC Guideline 301 D in a closed bottle test. There were charged 3,55 and 9,96 mg test substance per litre. Sodium acetate in a concentration of 5,17 and 9,68 mg per litre was the reference substance. The Inoculum originates in the discharge of a municipal sewage plant. The duration of the experiment was 28 days at a temperature of 20 +/- 1 °C. The chemical oxygen demand (COD) of the test substance was 0,169 mg/mg. Under these experimental conditions the test substance shows on average a degradability of 79 % BOD of the COD.

Evaluation:

The total degradability at the end is 79 % BOD of the COD. The test substance „DÜRR SYSTEM-HYGIENE OROTOL® PLUS Disinfection of Suction Systems" is to be classified as „easily biodegradable" under these test conditions.

Prof. Dr. B. Sonnenschein

i.V. U. Hamann

オロトルプラスのオオミジンコへの48時間急性毒性試験

BMG Engineering Ltd, 2008/03
48-hour Acute Toxicity to Daphnia magna

40体のオオミジンコを2つの試験容器に分け、0.063mg/L・0.125mg/L・0.25mg/L・0.5mg/L・1mg/Lのそれぞれの濃度に希釈したオロトルプラスに48時間暴露させた。
本試験はオオミジンコを48時間暴露した際の影響を調査し、10%以上のミジンコが有機化または水面に捕獲されなかった場合に妥当であると考える。培養24時間後、40体すべてのオオミジンコにおける有機化の割合は、濃度1mg/Lで25%であったがその他の濃度では影響が出なかった。培養48時間後は、濃度1mg/Lで62.5%、その他の濃度での影響はなかった。以上の結果より、48時間でオオミジンコに影響を及ぼす濃度は、0.866mg/Lであり、24時間および48時間暴露後に影響の出ない濃度は0.5mg/Lであることが検証された。48時間暴露後の1mg/L濃度にのみ100%有機化が認められた。

DÜRR SYSTEM-HYGIENE Orotol Plus
Sauganlagendesinfektion

48-hour Acute Toxicity to *Daphnia magna*

BMG report no. 277/b.2-08

March 2008

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

SWISS TESTING
S SCHWEIZERISCHER PRÜFSTELLENDIENST
T SERVICE SUISSE D'ESSAI
S SERVIZIO DI PROVA IN SVIZZERA
SWISS TESTING SERVICE STS-No. 166

1. SUMMARY

The median effective concentration (EC_{50}) of DÜRR SYSTEM-HYGIENE Orotol Plus Sauganlagendesinfektion to *Daphnia magna* was investigated under static exposure conditions over a period of 48 h.

40 individual Daphnia divided in 2 test vessels were exposed to each concentration of the test substance.

The nominal concentrations of DÜRR SYSTEM-HYGIENE Orotol Plus Sauganlagendesinfektion were 0.063, 0.125, 0.25, 0.5, and 1 mg/l, respectively. These test concentrations were prepared by corresponding dilution of stock solutions of the test substance.

No chemical analyses of the test media were conducted. For the calculation of the effective concentration leading to 0, 50, and 100% immobilization (EC_0, EC_{50}, EC_{100}) the nominal contents of the test solutions were used, assuming the test compound to be stable in water over 48 h.

After 24 h of incubation the following percentage of immobilization of the total of 40 individuals was observed:

1 mg/l (25%). No significant effects (<10% of a total of 40 individuals) were observed at 0.5, 0.25, 0.125 and 0.063 mg/l and in the blank control.

After 48 h of incubation the following percentage of immobilization of the total of 40 individuals was observed:

1 mg/l (62.5%). No significant effects (<10% of a total of 40 individuals) were observed at 0.5, 0.25, 0.125 and 0.063 mg/l and in the blank control.

Based on the immobilization data the nominal median effect concentration (EC_{50}) of DÜRR SYSTEM-HYGIENE Orotol Plus Sauganlagendesinfektion to *Daphnia magna* for 48 h was calculated to be 0.866 mg/l (95% confidence limits: 0.660–n.d.[1] mg/l). The EC_{50} for 24h was estimated to be >1 mg/l

The experimentally determined no-effect concentration (NOEC, EC_0) was 0.5 mg/l after an exposure of both, 24 and 48 h.

100% immobility (EC_{100}) was only observed in the range finding test at 1 mg/l after 48 h of exposure.

2. PURPOSE

The objective of this study was to determine the effects (NOEC, EC_{50} and EC_{100}) of DÜRR SYSTEM-HYGIENE Orotol Plus Sauganlagendesinfektion to *Daphnia magna* over a period of 48 h of exposure.

The test is considered valid if not more than 10% of the Daphnia in the control have been immobilized or trapped at the surface of the water. The dissolved oxygen concentration at the end of the test should not be < 60% of the air saturation value at the temperature used.

[1] n.d.: not detected

オロトルプラスの原料耐性試験

Orochemie, Dr. rer. nat. D. Heermann 1997/02/10
Expertise on the results of testing the material compatibility

歯科吸引システムにおいて使用されている異なる材料に対するオロトルプラスの原料耐性を検証するため、一般標準試験方法に加えて、特別デリケートな素材の吸引システムへの消毒性の比較試験も実施された。
<一般標準試験法による原料耐性試験> 40℃の2.0%希釈（50倍希釈）のオロトルプラスを使用し21時間に渡ってテストを行った結果、試験対象のすべての原料に適合を示した。
<比較試験> 標準試験に類似した方法を用いて2種類のOリングの膨張の程度を室温にて検証した結果、すべての組み合わせでほぼ膨張は見られず、膨張率のレベルはあらゆる点で以上に低かった。

OROCHEMIE
Dürr + Pflug GmbH + Co KG
(Research, Development, Technology)

Enzstrasse 20
Tel.: 07154 / 13 08 - 0
D-70806 Kornwestheim

February 10, 1997
Dr.HE/BR

DÜRR SYSTEM-HYGIENE
OROTOL® PLUS
Suction System Disinfection

Expertise
on the results of testing the material compatibility

The aim of the test was to determine the material compatibility of the developed formula of OROTOL® PLUS with the different materials that are used in dental suction systems. In addition to the regular standardized test procedure, a test with additional disinfectants for suction systems against particularly delicate materials was performed for comparison.

1. **Material compatibility test according to general standards**

   The samples of the materials were weighed and placed into a 2 % use solution of OROTOL® PLUS at 40 °C for 21 hours.

   The evaluation was made by changes in weight or possible visibly detectable changes.

   Result:
   All the materials that were tested are compatible with OROTOL® PLUS (see annex).

2. Comparative test within the OROTOL® product range

   For comparisosn, the extent of swelling on two different sorts of O-rings was determined. The mode of action was analogous to the standard test. In addition, this test was performed at room temperature.

   Result:
   In all test combinations, OROTOL® PLUS produced the lowest value of swelling possible. The total level of the swelling rates determined was extraordinarily low in every respect.

(Dr. rer.nat. D. Heermann)

(Dipl.-Ing. P. Brauner)

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

DÜRR DENTAL