DÜRR SYSTEM-HYGIENE
FD 312

Surface Disinfection

Concentrate for the simultaneous disinfection and cleaning
of washable surfaces and objects,
such as floors, walls, practice furniture, etc.

Effective 0510

PROF. DR. MED. H. - P. WERNER
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2008-08-12

DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion
Surface disinfection
Bactericidal and fungicidal (C. albicans) efficacy
Dirty conditions

EXPERTISE

After testing the disinfectant **DÜRR SYSTEM-HYGIENE FD 312 Flächen-desinfektion** in accordance with the

„Standard Methods of the DGHM for testing of chemical disinfection processes" (Status: 2001-09-01) I hereby issue the following evaluation of the results from the test report 2008-08-12 (SN 8108):

Results of the in vitro-tests

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

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

DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion resulted in sufficient reductions (5 lg. units of the test bacteria or 4 lg. units of C. albicans)

under **dirty** condition

in 2.0 %	within	5 minutes
in 1.0 %	within	15 minutes and
in 0.5 %	within	30 minutes.

Results under practical conditions

The efficacy of the disinfectant **DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion** was tested with mechanical action **under dirty condition** against the 4 test strains.

Under **dirty** condition resulted

in 2.0 %	within	5 minutes and
in 1.0 %	within	15 minutes

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

Application recommendations for
DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion
for surface disinfection with mechanical action

According to the results obtained, **DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion** complies with the

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

under dirty condition in

2.0 %	within	5 minutes and
1.0 %	within	15 minutes.

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

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Our Sign: Dr.Pi/mo

Date: 2010-02-09

Certificate

Of the product: **Dürr System Hygiene FD 312 Flächendesinfektion**

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").

The test reports dates 2007-04-16 and 2010-02-03. The investigated disinfectant sample was denominated "WF 213". According to the manufactures the composition of "WF 213" is identical with the product "Dürr System Hygiene FD 312 Flächendesinfektion".

This certificate has been replaced the certificate 2007-04-17, named "Gutachten PL 05-3 070417".

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.

I. Results of the in vitro tests

Neutralization test (Tab. 1 in the test report dating 2007-04-16)

Test organism	Concentration of the test product (%)	
	Without neutralizer	With optimal neutralizer
S. aureus	0.1	2.0
E. hirae	0.1	2.0
P. aeruginosa	0.5	>2.0
E. coli	0.1	2.0
P. mirabilis	0.5	>2.0
C. albicans	0.1	>2.0

The most effective neutralizer was:
3.0 % Tween 80, 3.0 % Lecithin, 0.1 % L-Histidin, 0.5 % Sodiumthiosulfate

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 2007-04-16)

Test organism	Concentration of the test product (%)
S. aureus	0.025
E. hirae	0.025
P. aeruginosa	0.25
E. coli	0.025
P. mirabilis	0.025
C. albicans	0.025

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 2007-04-16 and Tab. 1 test report dating 2010-02-03)

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	0.1	0.1	0.1
E. hirae	0.1	0.1	0.05	0.05
P. aeruginosa	2.0	1.0	0.75	0.5
C. albicans	0.5	0.5	0.5	0.5
All test organisms	**2.0**	**1.0**	**0.75**	**0.5**

II. Quantitative germ carrier tests (Tab. 7 - 14 in the test report dating 2007-04-16 and Tab. 2 test report dating 2010-02-03)

Sufficient reductions (> 5 lg for bacterial 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) and **with mechanic**:

1. Series

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

2. Series

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

III. Recommendation for the application as chemical disinfection of surfaces 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:

With mechanic, high organic burden:

5 min – 2.0 %
15 min – 1.0 %
30 min – 1.0 %
60 min – 1.0 %
240 min – 0.5 %

PD Dr. med. F.-A. Pitten
Managing director

DR. RER. NAT. WILFRIED PUCHERT
FACHCHEMIKER DER MEDIZIN
FACHCHEMIKER FÜR ANALYTIK UND SPEKTROSKOPIE

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DEUTSCHLAND

2009-09-25

DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion
Surface disinfection
Wipe disinfection - dirty conditions

EXPERTISE

Having tested the disinfectant **DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion** 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 2009-09-25 B 15799:

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 **dirty conditions.**

DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion results in sufficient reductions (5 lg units of test bacteria S. aureus, E. hirae and P. aeruginosa or 4 lg units of C. albicans)

under dirty conditions

in 2,0 %	within	5 minutes and
in 1,0 %	within	15 minutes.

*) DGHM = German society for Hygiene and Microbiology.

Results obtained in tests simulating conditions in practice

The efficacy of the disinfectant **DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion** was tested with mechanical action under **dirty conditions**.

Under **dirty conditions**

in 2,0 %	within	5 minutes and
in 1,0 %	within	15 minutes

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

Application recommendations for
DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion
for surface disinfection with mechanical action

According to the results obtained, **DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion** complies with the

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

under **dirty conditions**

in 2,0 %	within	5 minutes and
in 1,0 %	within	15 minutes.

Dr. rer. nat. Wilfried Puchert

*) VAH= Verbund für angewandte Hygiene

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Hamburg, 12 March 2006

Expert's report on the testing of the bactericidal effect of ***DÜRR SYSTEM-HYGIENE FD 312 FLÄCHENDESINFEKTION*** according to EN 13727: 2004 (phase 2, step 1)

Test report no. L 04/299.1 of Dr. Brill + Partner GmbH shows in accordance with EN 13727 (2004), that batch no. 30168 of ***"DÜRR SYSTEM-HYGIENE FD 312 FLÄCHENDESINFEKTION"*** has in dilution with hard water under high organic load (3 g/L sheep erythrocytes + 3 g/l bovine albumin) a bactericidal effect with reference to the tested germs *Staphylococcus aureus*, *Enterococcus hirae* and *Pseudomonas aeruginosa*. The following concentration-time relationships proved to be sufficiently effective:

0.5 %	**15 minutes**
0.25 %	**60 minutes**

Dr. Holger Brill

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Hamburg, 12 March 2006

Expert's report on the testing of the fungicidal effect of ***DÜRR SYSTEM-HYGIENE FD 312 FLÄCHENDESINFEKTION*** according to EN 13624: 2004 (phase 2, step 1)

Test report no. L 04/299.2 of Dr. Brill + Partner GmbH shows in accordance with EN 13624 (2004), that batch no. 30168 of "***DÜRR SYSTEM-HYGIENE FD 312 FLÄCHENDESINFEKTION***" has in dilution with hard water under high organic load (3 g/L sheep erythrocytes + 3 g/l bovine albumin) a fungicidal effect with reference to the tested germ *Candida albicans*. The following concentration-time relationship proved to be sufficiently effective:

0.25 % **15 minutes**

Dr. Holger Brill

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18th December 1984
Dr.Gr./E.-

DÜRR SYSTEM-HYGIENE
Surface Disinfection FD 312

Assessment

The tuberculocidal effectiveness of this product as a surface disinfectant was proven in a germ carrier test with Mycobacterium tuberculosis conducted according to I/2.4.2 of the "Guidelines for Testing and Assessing Chemical Disinfecting Methods, as of 01.01.1981".

As the results of our table reveal, complete inactivation of all test germs in a 1.0 %-solution was effected within a 60-minute action period:

Determination of the tuberculocidal effectiveness of DÜRR SYSTEM-HYGIENE Surface Disinfection FD 312 in the germ carrier test

Results of in vitro tests
(conducted according to I/2.4.2 of the Guidelines for Testing and Assessing Chemical Disinfecting Methods, as of 01.01.1981)

Application Concentration of disinfectant (%)	Action period (minutes) 5	15	30	60	120
0.5	+	+	+	+	+
1.0	+	+	+	-	-
Test Control with water of standardized hardness					+

+ = increase - = no increase

Inactivating combination: 3.0 % Tween 80, 3.0 % Saponin, 0.1 % histidine, 0.1 % cysteine

(Dr. R. Leimbeck)

(Dr. W. Grötsch)

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2005-08-23
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Vaccinia virus efficacy of DÜRR SYTEM-HYGIENE FD 312 FLÄCHENDESINFEKTION in a quantitative suspension test at 20°C

EXPERT OPINION

The virus-inactivating properties of the surface disinfectant DÜRR SYSTEM-HYGIENE FD 312 FLÄCHENDESINFEKTION of orochemie against vaccinia virus strain Elstree were investigated by a quantitative suspension test according to the guideline of the Bundesgesundheitsamt (BGA, Federal Office of Health, now Robert Koch-Institut) and the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (German Association for the Control of Virus Diseases).
According to this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$ (inactivation ≥ 99,99%).

The disinfectant was examined as 1.0% solution at 20°C. Exposure times were 0.5, 1.0, 2.0, 5.0 and 30.0 minutes. After an exposure time of 0.5 and 5.0 minutes respectively virus reduction exceeded 4 $\log_{10}$ steps. Due to the lack of guidelines simulating practical conditions, results of the quantitative suspension test lead to the recommendation to use the surface disinfectant DÜRR SYSTEM-HYGIENE FD 312 FLÄCHENDESINFEKTION for inactivation of vaccinia virus as follows:

without soil load	**1.0%**	**0.5 minutes**
with soil load	**1.0%**	**5.0 minutes**

Dr. J. Steinmann

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BVDV efficacy of DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion

EXPERT'S INVESTIGATION REPORT

The virucidal efficacy of the disinfectant DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion 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 FD 312 Flächendesinfektion was examined as a 1.0% 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 DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion for the inactivation of BVDV as follows:

without soil load	**1.0 %**	**1 min.**
with soil load	**1.0 %**	**2 min.**

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30.09.2008
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Efficacy of DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion against MNV in a quantitative suspension test at 20°C following EN 14476:2007-02 under dirty conditions

EXPERT OPINION

This expert opinion is based on the test report 08ML661BM dating 30.09.2008.

The virus-inactivating properties of the surface disinfectant DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion of orochemie GmbH & Co KG against murine norovirus (MNV) were investigated by a quantitative suspension test following EN 14476:2007-02 under dirty conditions.

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

According to 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 312 Flächendesinfektion was examined as 2.0 % and 4.0 % solutions at 20°C. The exposure times were 30, 60, 120 and 240 minutes. After an exposure time 30 minutes (4.0 %) virus reduction exceeded 4 $\log_{10}$-steps. Therefore, a virucidal activity against MNV under dirty conditions was measured as follows:

4.0 % **30 min**

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22nd May 1987 / ti

Project No. 1-4-337-87

DÜRR SYSTEM-HYGIENE
FD 312
Surface Disinfection

Expertise

on the results of testing the acute oral toxicity in rats, in conformity with the OECD guidelines.

I. The test was carried out in order to establish whether the test substance FD 312 would cause toxic effects in rats after a single oral dose. The medium lethal dose was to be determined over a 14-day follow-up period.

This test was carried out in accordance with the Good Laboratory Practice Regulations (U.S. Fed. Reg., Title 21, Dec 22, 1978, part II).

II. SUMMARY

Five male and five female Wistar rats were used for acute oral toxicity testing. Throughout the entire observation period, clinical-toxicological symptoms were recorded, and the acute mortalities, i.e. those animals which were sacrificed at the end of the experiment, were examined for gross organ changes inside the skull, chest and abdomen.

Under the test conditions described below it was found:

a) The preparation caused reduced activity, disturbances of coordination, abnormalities of posture and position, diminished excitability of reflexes, piloerection, cyanosis and reduced respiratory frequency.

b) At the end of the 14-day follow-up period, the surviving animals showed normal weight development in comparison with the baseline.

c) The moribund sacrificed animal showed haemorrhoids in the small intestine's mucous membrane and accumulations of fluid in the alimentary canal.
There were no findings at the final dissection (14 days p.a.).

d) Calculation of the oral LD_{50} by means of the Probit analysis according to Finney gave the following results:

24 h	ml / kg		mg / kg
male			
female	> 7.5	(estimated)	> 7913
male + female			
48 h			
male	5.43 (4.22 - 14.75)		5730 (4456 - 15550)
female	6.17 (5.09 - 14.44)		6508 (5367 - 15233)
male + female	5.79 (4.86 - 9.10)		6109 (5127 - 9599)
3 / 14 days			
male	5.43 (4.22 - 14.75)		5730 (4456 - 15550)
female	5.21		5498
male + female	5.32 (4.27 - 8.53)		5613 (4503 - 8994)

e) According to the GefStoff of Aug 26, 1986 (BGBI Federal Gazette 1470), page 7, the product, if administered in a single oral dose, is "of low toxicity".

(Dr. Dr. W. Sterner)

(Dr. G. Chibanguza)

Harlan
BIOSERVICE
FOR SCIENCE

Final Report

Dürr System-Hygiene FD 312 Flächendesinfektion:
Study on Acute Dermal Toxicity in the Rat

Study No.: **10-4-0156/01-06**

Sponsor: **orochemie Dürr + Pflug GmbH + Co KG**
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FOR SCIENCE

Study Schedule

Experimental Starting Date: 11 October 2006

Experimental Completion Date: 7 November 2006

Study Completion Date: 12 December 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.

D. Marburger — 12-DEC-2006

Dr. A. Marburger
Study Director

Date

K.-J. Kühne — 12 DEC 2006

K.-J. Kühne
Responsible Technician

Date

Harlan
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FOR SCIENCE

1 Summary

The potential toxicity of Dürr System-Hygiene FD 312 Flächendesinfektion was assessed in an acute dermal toxicity test on a total of ten Wistar rats (five males and five females).

On the basis of the range finding test, the animals received a single dermal dose of 2000 mg/kg of the test article. The skin was exposed to the test article for 24 hours. After treatment, animals were observed for 14 days including daily clinical observations and regular body weight recordings. Fourteen days after treatment all animals were euthanised and macroscopically examined.

The following results were obtained:

- All animals survived until scheduled necropsy and no systemic clinical signs were noted throughout the study period.
- Body weight loss was noted for all females during the first week after treatment. For two females further body weight loss was noted during the second week. Reduced body weight gain was noted for all males during the first week after treatment.
- Reactions (mainly eschar formation) of the treated skin were noted for three males and five females.
- Macroscopic findings during necropsy were confined to alterations of the treated skin. For one male peeling-off eschar was noted and for five females eschar - firmly connected to the skin - was noted.

In conclusion, it can be stated that following an acute dermal administration of Dürr System-Hygiene FD 312 Flächendesinfektion at a dose 2000 mg/kg slight signs of systemic toxicity evident as body weight loss (females) or reduced body weight gain (males) were noted.

Assessment

Since no mortalities were noted in Wistar rats of both genders after dermal treatment with the test article at a dose of 2000 mg/kg, the LD_{50} value after 24 hours as well as 14 days was > 2000 mg/kg.

This value is higher than the limit specified as harmful by the EEC Directive 2001/59/EEC of 6 August 2001 and the Gefahrstoffverordnung (GefStoffV) of 23 December 2004 (BGBl. I, p. 3855). When administered by the dermal route, the test article

Dürr System-Hygiene FD 312 Flächendesinfektion

is therefore classified as **"non-toxic"**.

RCC-CCR STUDY NUMBER 1042300

IN VITRO SKIN IRRITATION TEST:
HUMAN SKIN MODEL TEST

WITH

DÜRR SYSTEM-HYGIENE FD 312
FLÄCHENDESINFEKTION

FINAL REPORT

Study Completion Date: September 28, 2006

RCC

1 CONTENTS

2.4 Project Staff Signatures

Study Director Dipl. Biol. Krista Meurer

Date: September 28, 2006

Management Dr. Wolfgang Völkner

Date: September 28, 2006

2.5 Guidelines

There are no internationally accepted Guidelines available. The test will be performed as described in this study plan.

7 DISCUSSION

This *in vitro* study was performed to assess the irritation potential of DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion by means of the Human Skin Model Test.

Three tissues of the human skin model EpiDerm™ 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 ≥ 0.8 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 11.1 %, for the 15 minutes treatment interval thus ensuring the validity of the test system.

After treatment with the test item DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion the relative absorbance values were decreased to 13.5 %. This value is well below the threshold for irritancy of ≤ 50 %. Therefore, the test item is considered to possess an irritant potential.

8 CONCLUSION

In conclusion, it can be stated that in this study and under the experimental conditions reported, the test item DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion is **irritant** to skin.

Harlan
BIOSERVICE
FOR SCIENCE

Final Report

Dürr System-Hygiene FD 312 Flächendesinfektion:
Maximisation Sensitisation Test in the Guinea Pig

Study No.: **10-5-0158/01-06**

Sponsor: **orochemie Dürr + Pflug GmbH + Co KG**
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Harlan BIOSERVICE FOR SCIENCE

General Information

Study Title	Dürr System-Hygiene FD 312 Flächendesinfektion: Maximisation sensitisation test in the guinea pig
Study Number	10-5-0158/01-06
Sponsor	orochemie Dürr + Pflug GmbH + Co KG Postfach 16 30 70798 Kornwestheim Germany
Study Monitor	Dr. K.-M. Wolf Tel.: 07154 / 13 08 27
Testing Facility	*Harlan Bioservice for Science GmbH* Südkampen 31 29664 Walsrode Germany

Responsibilities

Testing Facility Management	Dr. med. vet. Frank Baumann
Study Director	Dr. med. vet. Andrea Marburger *Veterinarian* E-mail: marburger@harlanbioservice.com
Deputy Study Director	Dr. med. vet. Holger Schmidt *Veterinary Specialist for Pharmacology and Toxicology* E-mail: schmidt@harlanbioservice.com
Responsible Technician	K.-J. Kühne

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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.

D. Marburger — 23-OCT-2006

Dr. A. Marburger
Study Director

Date

K.-J. Kühne — 23-OCT-2006

K.-J. Kühne
Responsible Technician

Date

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1 Summary

The potential skin sensitising properties of the test article "Dürr System-Hygiene FD 312 Flächendesinfektion" 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 1% 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 of 6 August 2001 and the Gefahrstoffverordnung (GefStoffV), 23 December 2004 (BGBl. I, p. 3855), the test article

Dürr System-Hygiene FD 312 Flächendesinfektion

at the intended working concentration (i.e. a 1% 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.

DÜRR-SYSTEM-HYGIENE FD 312
Flächendesinfektion

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

CLOSED BOTTLE TEST

BMG report no. 877.3-06

September 2006

BMG

Labors: Analytik, Ökotoxikologie,
Verfahrenstechnik

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1. SUMMARY

The biodegradability of DÜRR-SYSTEM-HYGIENE FD 312 Flächendesinfektion 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 312 Flächendesinfektion based on O_2 consumption was calculated to be 63 % after 28 days as compared to the chemical O_2 demand (COD).

The procedure control sodium benzoate reached 77 % biodegradation after 14 days, thus confirming suitability of inoculum and test conditions.

According to the sponsor all surfactants used in preparation DÜRR-SYSTEM-HYGIENE FD 312 Flächendesinfektion meet the criteria of the Detergent Regulation 2005/648/EC. DÜRR-SYSTEM-HYGIENE FD 312 Flächendesinfektion, too reached the pass level of 60 % for ready biodegradability in the Closed Bottle Test after 28 days, therefore confirming the results obtained with the individual surfactants. DÜRR-SYSTEM-HYGIENE FD 312 Flächendesinfektion can be termed as readily biodegradable.

2. PURPOSE

The objective of this study was to determine the ready biodegradability of DÜRR-SYSTEM-HYGIENE FD 312 Flächendesinfektion under aerobic static exposure conditions using the Closed Bottle Test.

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

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

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

6. SIGNATURE

It is certified that the test for ready biodegradability of DÜRR-SYSTEM-HYGIENE FD 312 Flächendesinfektion was carried out under the study director's supervision using the guidelines and standard operating procedures described in this report and that this report forms a true and accurate record of the procedures performed and of the results obtained.

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

.....
Dr. A. Häner (Study Director)

.....26 September 2006.....
Date

DÜRR SYSTEM-HYGIENE FD 312
Flächendesinfektion

48-hour Acute Toxicity to *Daphnia magna*

BMG report no. 277/a.1-08

March 2008

BMG

Labors: Analytik, Ökotoxikologie,
Verfahrenstechnik

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1. SUMMARY

The median effective concentration (EC_{50}) of DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion 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 FD 312 Flächendesinfektion 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 (85%), 0.5 mg/l (35%). No significant effects (<10% of a total of 40 individuals) were observed at 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 (100%), 0.5 mg/l (90%), 0.25 mg/l (47.5%). No significant effects (<10% of a total of 40 individuals) were observed at 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 FD 312 Flächendesinfektion to *Daphnia magna* for 24 and 48 h was calculated to be 0.589 mg/l (95% confidence limits: 0.501–0.724 mg/l) and 0.260 mg/l (95% confidence limits: 0.229–0.302 mg/l), respectively.

The experimentally determined no-effect concentration (NOEC, EC_0) was 0.25 mg/l and 0.125 mg/l after an exposure of 24 and 48 h, respectively.

100% immobility (EC_{100}) was seen at the nominal concentration of 1 mg/l after an exposure of 48 h.

2. PURPOSE

The objective of this study was to determine the effects (NOEC, EC_{50} and EC_{100}) of DÜRR SYSTEM-HYGIENE FD 312 Flächendesinfektion 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.

7th of October, 1998
HE/WF

DÜRR SYSTEM-HYGIENE
FD 312
Surface Disinfection

Expertise

on the results of testing the material compatibility of FD 312

It had to be checked with the described examination, if there are any material incompatibilities when using FD 312 for surface disinfection of wetly blendable surfaces (materials, which are used for exemple for floors, cupboards, drawers, dental chairs, tables, etc.). The tested materials are a typical example for a dental chair, tables and cupboards as well as floors.

The tests were carried out as follows:
The surfaces to be tested were wetted completely with a rag at room temperature with a 1 % ready-to-use-solution of FD 312. After that the surface was being dried for an hour, wiped up with a damp cloth and dried by rubbing. The test was then repeated.

Altogether 50 test cycles were carried out within a period of approx. two weeks.

After completion of the tests it was checked if there were changes of surfaces such as changes in color, formation of bubbles, roughnesses, detachments, etc.

Result:

At the different tested materials no visually recognizable changes arose. Material defects caused by FD 312 couldn't be detected.

(Dr. rer.nat. D. Heermann)

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