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

ID212 instrument disinfection
インスツルメント｜器具の除菌

2019年5月現在

DÜRR DENTAL

個別診断／試験結果／効能証明書
ID212 instrument disinfection
インスツルメント｜器具の除菌

DGHMのガイドラインに沿った定量浮遊実験

Dr.Rer Nat Holger Brill 2005/07/19

Summary of the tests carried out in accordance with the DGHM-standard methods

ID212の静菌性と静真菌性をDGHMのガイドラインに沿って定量的浮遊実験を行いました。
マイコバクテリウム・テラエまたはアスペルギルスの汚染条件下でない場合は、濃度2.0%に対し5分または濃度1.0%で15分の作用時間が推奨されます。アスペルギルスの汚染下では濃度4.0%の時、60分の作用時間が推奨されています。

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Orochemie Dürr + Pflug GmbH & Co. KG
Max-Planck-Straße 27
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Hamburg, 19 July 2005

Summary of the tests carried out in accordance with the DGHM-standard methods

The instrument disinfectant ***DÜRR SYSTEM-HYGIENE ID 212 INSTRUMENTENDESINFEKTION*** was tested in accordance with the " DGHM standard methods for testing chemical disinfection procedures" dated 1 September 2001 and evaluated according to the "List of requirements for inclusion of chemical disinfection procedures in the DGHM list of disinfectants" dated 4 February 2002.

The test preparation proved to be bactériostatic and fungistatic as well as bactericidal and fungicidal. In addition, the test preparation is effective against the mould fungus *Aspergillus niger*.

The use-recommendation for ***DÜRR SYSTEM-HYGIENE ID 212 INSTRUMENTENDESINFEKTION*** for chemical instrument disinfection without *Mycobacterium terrae* and *Aspergillus niger* is:

2.0 %	5 minutes
1.0 %	15 minutes

The use-recommendation for ***DÜRR SYSTEM-HYGIENE ID 212 INSTRUMENTENDESINFEKTION*** for chemical instrument disinfection including the efficacy against *Aspergillus niger* is:

4.0 %	60 minutes

Dr. Holger Brill

DGHMのガイドラインに沿ったID212の効力の検証

PD Dr.med.F.-A.Pitten 2008/09/04
Chemical disinfection of instruments used in the medical area

ID212の化学消毒剤の有効性をDGHMのガイドラインに従い検証し、各ウイルスに対する効果の詳細が表に示されています。
試験の結果高い有機負荷では濃度2%に5分の作用時間が消毒に効果的と証明されています。

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Our Sign
Dr.Pi/mo

Date
4th September 2008

Expert Opinion

Of the product: **DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion**

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 2008-09-04.

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.

Results of the in vitro tests
Neutralization test (Tab. 1 in the test report dating 2008-09-04)

Test organism	Concentration of the test product (%)	
	without neutralizer	with optimal neutralizer
S. aureus	0.1	1.0
E. hirae	0.025	2.0
P. aeruginosa	0.75	>2.0
E. coli	0.025	1.0
P. mirabilis	0.25	>2.0
C. albicans	≤ 0.0125	1.5

The most effective neutralizer was:
3.0 % polysorbate 80, 3.0 % saponin, 0.1 % L-histidine, 0.1 % L-cysteine

This neutralizer was applied in all subsequent trials.

Assessment of the bactericidal and levurocidal efficacy in the qualitative suspension (Tab. 2 in the test report dating 2008-09-04)

Test organism	Effective concentration (%) at time of action			
	5 min	15 min	30 min	60 min
S. aureus	0.75	0.5	0.1	≤ 0.05
E. hirae	1.0	0.75	0.5	0.25
P. aeruginosa	1.0	0.75	0.5	0.1
E. coli	0.5	0.25	0.1	0.1
P. mirabilis	0.75	0.5	0.25	0.25
C. albicans	0.25	0.1	0.1	≤ 0.05

Assessment of the bactericidal and levurocidal efficacy in the quantitative suspension test (Tab. 3 – 10 in the test report dating 2008-09-04)

Sufficient reductions 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% bovine albumin solution and 0.3% sheep erythrocytes):

Test organism	Effective concentration (%) at time of action			
	5 min	15 min	30 min	60 min
S. aureus	0.1	0.1	0.1	0.1
E. hirae	0.1	0.1	0.1	0.1
P. aeruginosa	2.0	2.0	2.0	2.0
C. albicans	1.0	0.5	0.25	0.25
All test organisms	**2.0**	**2.0**	**2.0**	**2.0**

Quantitative germ carrier tests (Tab. 11 - 18 in the test report dating 2008-09-04)

Sufficient reductions of the test organisms S. aureus, E. hirae, P. aeruginosa and C. albicans were yielded using the following relations of time of action and concentration of the test product with **high organic burden** (0.3% bovine albumin solution and 0.3% sheep erythrocytes):

Test organism	**Effective concentration (%) at time of action**			
	5 min		**15 min**	
	1. SR	2. SR	1. SR	2. SR
S. aureus	0.5	1.0	0.5	0.5
E. hirae	0.5	0.5	0.5	0.5
P. aeruginosa	1.0	2.0	0.5	1.0
C. albicans	0.5	1.0	0.5	0.5
All test organisms	**1.0**	**2.0**	**0.5**	**1.0**

SR = Series nd = not done

Recommendation for the application as chemical 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:

high organic burden:

5 min time of action and **2 %** concentration.

PD Dr. med. F.-A. Pitten

EN13727:2003に準したID212の殺菌力の検証

Dr.Rer Nat Holger Brill 2004/10/12

Determination of bactericidal effect of ID212 according to EN13727:2003

EN13727:2003に従いID212の殺菌性を検証しました。ID212を高有機負荷条件下（3g/l羊赤血球+3g/ウシアルブミン）で標準高度の水で希釈したとき、黄色ブドウ球菌または緑膿菌に対し有効であり、濃度2.0%の時5分または濃度1.0%の時60分の作用時間が有効であると証明されています。

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Determination of bactericidal effect of

DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion according to EN 13727: 2003

a) Identification of test laboratory

Dr. Brill + Partner GmbH - Labor für Hygiene und Mikrobiologie, Papenreye 61, 22453 Hamburg; Dr. Holger Brill, Margret Becker

b) Identification of test material

• Name of product:	DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion
• Batch number:	21125
• Manufacturer:	orochemie Dürr + Pflug GmbH & Co. KG, Kornwestheim
• Date of delivery:	12.10.2004
• Terms of storage:	Room temperature and darkness
• Appearance of product and its dilutions:	clear, blue solution
• Odour:	aromatic
• pH value, concentrate:	11.6
• pH value, 4 %ig:	11.0
• pH value, 2 %ig:	9.7
• pH value, 1 %ig:	9.2
• Recommended diluent:	Drinking water
• Active agents in 100 g product:	9.0 g alkyl-benzyl-dimethyl-ammonium chloride 0.1 g guanidine compound

c) Test procedure and its validation:

• Test procedure:	Quantitative suspension test (Phase 2/Stufe 1)
• Method:	Dilution-neutralisation method
• Neutralisation medium:	30 g/L polysorbate 80; 30 g/L saponine; 1 g/L histidine; 1 g/L cysteine (TSHC)

d) Test conditions

– Period of testing:	01.03.2005 until 18.03.2005	
– Product diluent:	sterile water of standardised hardness, 300 mg/kg $CaCO_3$	
– Product test concentrations:	1.0; 2.0; 3.0; 4.0 % volume concentration	
– Exposure times:	5, 15, 60 minutes	
– Test temperature:	20°C ± 1°C	
– Organic load, high:	3 g/L sheep erythrocytes + 3 g/L bovine serum albumine	
– incubation temperature:	36°C ± 1°C	
– Identification of microbial strains used:	Staphylococcus aureus	ATCC 6538
	Enterococcus hirae	ATCC 10541
	Pseudomonas aeruginosa	ATCC 15442

e) Test results

The test results are summarised in table 1 to 3.

f) Conclusions

In accordance with prEN 13727 (2003), the batch 21125 of the product ***„DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion"*** shows in a dilution with water of standardised hardness under a high organic load (3 g/L sheep erythrocytes + 3 g/l bovine albumine) a bactericidal effect with regard to the germs tested Staphylococcus aureus, Enterococcus hirae and Pseudomonas aeruginosa. The following concentration-time-relationships proved to be sufficiently effective:

2.0 % 5 minutes
1.0 % 60 minutes

g) Hamburg, 21.03.2005, Dr. Holger Brill

カンジタ・アルビカンス汚染条件下でのID212の殺菌性の検証

Dr.Rer Nat Holger Brill 2004/10/12

Determination of fungicidal effect of ID212 instrumentendesinfektion according to EN13624:2003

EN13624:2003に従いID212の殺菌性を検証しました。ID212を高有機負荷条件下（3g/l羊赤血球+3g/ウシアルブミン）で標準高度の水で希釈したとき、カンジダ・アルビカンス有効であり、濃度2.0%の時5分または濃度1.0%の時15分の作用時間が有効であると証明されています。

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Determination of fungicidal effect of

DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion according to EN 13624: 2003

a) Identification of test laboratory

Dr. Brill + Partner GmbH - Labor für Hygiene und Mikrobiologie, Papenreye 61, 22453 Hamburg; Dr. Holger Brill, Margret Becker

b) Identification of test material

• Name of product:	DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion
• Batch number:	21125
• Manufacturer:	orochemie Dürr + Pflug GmbH & Co. KG, Kornwestheim
• Date of delivery:	12.10.2004
• Terms of storage:	Room temperature and darkness
• Appearance of product and its dilutions:	clear, blue solution
• Odour:	aromatic
• pH value, concentrate:	11.6
• pH value, 4 %:	11.0
• pH value, 2 %:	9.7
• pH value, 1 %:	9.2
• Recommended diluent:	Drinking water
• Active agents in 100 g product	9.0 g alkyl-benzyl-dimethyl-ammonium chloride 0.1 g guanidine compound

c) Test procedure and its validation

• Test procedure:	Quantitative suspension test (phase 2/step 1)
• Method:	Dilution-neutralisation method
• Neutralisation medium:	30 g/L polysorbate 80; 30 g/L saponine; 1 g/L histidine; 1 g/L cysteine (TSHC)

d) Test conditions

– Period of testing:	01.03.2005 until 18.03.2005
– Product diluent:	sterile water of standardised hardness, 300 mg/kg $CaCO_3$
– Product test concentrations:	1.0; 2.0; 3.0; 4.0 % volume concentration
– Exposure times:	5, 15, 60 minutes
– Test temperature:	20°C ± 1°C
– Organic load, high:	3 g/L sheep erythrocytes + 3 g/L bovine serum albumine
– Incubation temperature:	36°C ± 1°C
– Identification of fungus strains used:	Candida albicans ATCC 10231

e) Test results

The test results are summarised in table 1.

f) Conclusions

In accordance with prEN 13624 (2003), the batch 21125 of the product ***„DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion"*** shows in a dilution with water of standardised hardness under a high organic load (3 g/L sheep erythrocytes + 3 g/l Bovine albumine) a fungicidal effect with regard to the germ tested Candida albicans. The following concentration-time-relationships proved to be sufficiently effective:

2.0 % 5 minutes
1.0 % 15 minutes

g) Hamburg, 21.03.2005, Dr. Holger Brill

EN14561:2005に準したID212の殺菌力の検証

Dr.Rer Nat Holger Brill 2006/03/12

Testing of the bactericidal effect of ID212 according to EN14561:2005

IEN14561:2005に従いID212の殺菌性を検証しました。ID212を高有機負荷条件下（3g/l羊赤血球+3g/ウシアルブミン）で標準高度の水で希釈したとき、黄色ブドウ球菌、エンテロコッカス・ヒラエまたは緑膿菌に対し有効であり、濃度1.0%の時5分、濃度0.5%15分または60分の作用時間が有効であると証明されています。

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Hamburg, 12 March 2006

Expert's report for the testing of the bactericidal effect of ***DÜRR SYSTEM-HYGIENE ID 212 INSTRUMENTENDESINFEKTION*** according to EN 14561: 2005 (phase 2, step 2)

The test report no. L 04/254.3 of Dr. Brill + Partner GmbH shows in accordance with EN 14561 (2005), that batch no. 21125 of ***"DÜRR SYSTEM-HYGIENE ID 212 INSTRUMENTENDESINFEKTION"*** 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 test germs *Staphylococcus aureus, Enterococcus hirae* and *Pseudomonas aeruginosa*. The following concentration-time relationships proved to be sufficiently effective:

1.0 %	**5 minutes**
0.5 %	**15 minutes**
0.5 %	**60 minutes**

Dr. Holger Brill

EN14561:2005に準したID212の殺真菌性の検証

Dr.Rer Nat Holger Brill 2006/03/12

Testing of the fungicidal effect of ID212 according to EN14562:2005

IEN14562:2005に従いID212の殺菌性を検証しました。ID212を高有機負荷条件下（3g/l羊赤血球+3g/ウシアルブミン）で標準高度の水で希釈したとき、カンジダ・アルビカンスまたはアスペルギルスに対し効力があることが証明されています。カンジダ・アルビカンスに対しては、濃度1.0%の時5分、濃度0.5%15分または60分の作用時間が有効です。アスペルギルスの汚染条件下では濃度4.0%に対し5分、3.0%15分または60分の作用時間が十分効果的であると証明されています。

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Hamburg, 12 March 2006

Expert's report for the testing of the fungicidal effect of ***DÜRR SYSTEM-HYGIENE ID 212 INSTRUMENTENDESINFEKTION*** according to EN 14562: 2005 (phase 2, step 2)

The test report no. L 04/254.4 of Dr. Brill + Partner GmbH shows in accordance with EN 14562 (2005), that batch no. 21125 of ***"DÜRR SYSTEM-HYGIENE ID 212 INSTRUMENTENDESINFEKTION"*** 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 test germs *Candida albicans* and *Aspergillus niger*.

The following concentration-time relationships proved to be sufficiently effective against *Candida albicans* (laeverucidal effect):

1.0 %	**5 minutes**
0.5 %	**15 minutes**
0.5 %	**60 minutes**

The following concentration-time relationships proved to be sufficiently effective against *Aspergillus niger* (fungicidal effect):

4.0 %	**5 minutes**
3.0 %	**15 minutes**
3.0 %	**60 minutes**

Dr. Holger Brill

ID212の器具除菌の適正の検証

Dr.med.Burkhard Wille 1992/06/10

The suitability as chemical instrument disinfectant of the preparation

DGHMのガイドラインに従いID212の結核菌の汚染条件下での器具除菌の適正を検証した結果、濃度2.0%に対し60分の作用時間が推奨さてています。

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Physician for Microbiology and Infection Epidemiology
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Tel. 0641/13011 and 72091

10th June 1992

Special Hygiene Expertise
on the suitability as chemical instrument disinfectant of the preparation

DÜRR SYSTEM-HYGIENE
ID 212 Instrument Disinfection

On 2nd April 1992 we received the order to carry out our expertise of 18.4.1986 on the microbicidal effect of the preparation **Dürr System-Hygiene Instrument Disinfection ID 212** for use as chemical instrument disinfectant according to the DGHM guidelines "Testing and Assessing Chemical Disinfecting Methods" (as of 12.7.1991).

The tests assessed by the expertise of 1986 were conducted in conformity with the "Guidelines for Testing and Assessing Chemical Disinfecting Methods, 1st Section (as of 01.01.1981)" and "Testing and Assessing Chemical Disinfecting Methods (as of 01.02.1984)". The determination of the tuberculocidal effect in the modified germ-carrier tests was carried out in 1992.

For the determination of the bactericidal effect in the quantitative tests, the method indicated in the a.m. Guidelines was modified by the use of a spiral platers, model CU, of Spiral-Systems Inc.

According to the manufacturer's specifications the examined preparation without batch number dated 11.02.1986 (06.04.1992) is based on quaternary ammonium compounds, biguanides, non-ionic surfactants and alkali cleaning components. The blue transparent liquid concentrate with an aromatic smell had a pH value of 11.8 (11.8), while in a 2.0 % concentration its pH value was 10.4 (10.4).

RESULTS

In determining the bacteriostatic and fungistatic effectiveness, as well as suitable inactivation substances, the most effective disinhibiting combination for the germs tested consisted of 3.0 % Tween 80, 3.0 % saponine, 0.1 % histidine, and 0.1 % cysteine. The following micro-organisms multiply at the specified disinfectant concentration levels: up to 0.05 % Candida albicans, up to 0.25 % Staphylococcus aureus, up to 1.0 % Streptococcus faecalis, up to 1.5 % Escherichia coli, and up to 2.0 % Proteus mirabilis and Pseudomonas aeruginosa (see Tables 1- 4).

The quantitive suspension test revealed a microbicidal effectiveness at 0.5 % of the examined disinfectant and a 60-minute action period. Staphylococcus aureus and Pseudomonas aeruginosa were subjected to quantitative suspension tests (see Table 5).

A germ reduction by ≥5 log orders was achieved with Staphylococcus aureus in 0.1 % disinfectant concentration and a 60-minute action period. A germ reduction by ≥5 log orders was achieved with Pseudomonas aeruginosa in 0.5 % disinfectant concentration and a 60-minute action period. The albumin error is moderate (see tables 6 + 7).

The required effectiveness was achieved in the practice-related tests with rubber tubes, at a 1-hour action period and 2.0 % disinfectant solution. The tests were duplicated (see Table 8).

The determination of the tuberculocidal effect by the modified germ-carrier test without inactivating substances revealed that Mycobacterium terrae was killed by a 2.0 disinfectant solution within a 60-minute action period (see Table 9).

The determination of the tuberculocidal effect by the modified germ-carrier test with inactivating substances revealed that Mycobacterium terrae was killed by a 2.0 % disinfectant concentration and a 60-minute action period as well as a 120-minute action period at a 1.5 % disinfectant concentration (see Table 10).

ASSESSMENT

The preparation **DÜRR SYSTEM-HYGIENE Instrument Disinfection ID 212** is suitable for chemical instrument disinfection at a 2.0 % concentration within a 60-minute action period.

SUMMARY

Based on the results gained from testing the preparation **DÜRR SYSTEM-HYGIENE Instrument Disinfection ID 212** in conformity with the "Guidelines for Testing and Assessing Chemical Disinfection Methods, 1st Section (as of 01.01.1981)" and "Testing and Assessing Chemical Disinfecting Methods (as of 12.07.1991)", the product can be recommended as a chemical instrument disinfectant.

Recommended application for instrument disinfection:
2.0 % concentration and a 60-minute action period

(Dr. W.U. Färber)

(Prof. Dr. med. B. Wille)

ID212の除菌力の検証

Helsinki University 1987/04/09

The results of testing the disinfecting strength of the ID212 disinfectant

非汚染条件下では濃度1.0%で細菌（黄色ブドウ球菌、大腸菌、緑膿菌）の除菌に十分でしたが、有機負荷可では緑膿菌を殺すのに4.0%の溶液が必要であると証明されています。

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April 9, 1987

DÜRR SYSTEM-HYGIENE
ID 212
Disinfection of instruments

Expertise
on the results of testing the disinfecting strength of the ID 212 disinfectant

The substance to be examined was the ID 212 disinfectant (manufactured by Dürr System-Hygiene). According to the manufacturers, its active disinfecting ingredient is 5 to 10 % of benzalconium chloride. The product is intended for the disinfection of instruments used in dental care.

The purpose of the examination carried out was to establish the disinfecting effect of the product in laboratory tests in a clean environment and in the presence of an organic substance.

The examination procedure

The examination method used was the modified Kelsey Test (The Pharmaceutical Journal 202: 607-609, 1969). In this test the effect of the disinfectant is examined both in the presence and in the absence of an organic substance. 2% yeast cells, which had been mixed with a suspension of bacterial cells, were used as an organic substance.

The examination was conducted in the following overall manner: 1 ml of the bacterial suspension, which had been cultivated in meat broth overnight, was added to 3 ml of the disinfectant solution. A sample of the suspension was taken after 8 minutes to establish whether there were still living bacteria in it. At the second stage of the examination, two minutes later, bacterial suspension was again added and another sample was taken after a delay of 8 minutes. This procedure was then repeated for a third time. Bacterial growth was recorded on a qualitative basis (+/-).

The micro-organisms used for the test were *Staphylococcus aureus* NTC 3163, *Escherichia coli* NCTC 8196 and *Pseudomonas aeruginosa* NCTC 6749. The water used for the test was the so-called standard hard water as defined by the WHO, hardness approximately 300 ppm. The tests were conducted at room temperature. The diluted product solutions were examined in concentrations of 1%, 1.5%, 2%, 3% and 4%.

Results

The results are shown in the attached Table. In a clean environment the product killed the bacteria examined in the recommended 1% solution. In the presence of an organic substance a 4% solution was required to kill Pseudomonas aeruginosa.
By way of comparison it could be mentioned that, in the presence of an organic substance, the Gavisol and Ivisol products which contain phenolic compounds killed the bacteria under examination in a 1% concentration.

Enclosure: 1 Table

Juhani Ojajärvi, LKT, laboraattori
(Doctor of Medicine and Surgery, Head of the Laboratory)

ID212の殺菌性の証明

Laboratoire Midac 1997/07/09

Determination of the basic bactericidal activity of ID212

ID212はヨーロッパ規格EN1040に準した基本的な殺菌活性を有しています。

MIDAC LABORATOIRE

Etude, Conseil, Expertise et Formation en Microbiologie.

Test Report n ° 97 219 CEN-2.

cofrac ESSAIS LABORATOIRE ACCRÉDITÉ SOUS LE N° 1-0019

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

Object : Determination of the basic bactericidal activity of **ID 212**
(your ref. : 97.05.23 fax)

L'accréditation par la Section Essais du COFRAC atteste uniquement de la compétence technique du laboratoire pour les essais ou analyses couverts par l'accréditation.

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Il comporte 4 pages et 0 annexe.

CONCLUSION :

In the specified operating conditions and for the sample under test, the product ID 212 (97.04.25 sample) has a basic bactericidal activity in accordance with the european standard EN 1040.

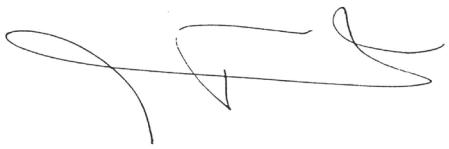
(To qualify the product as antiseptic and/or disinfectant for a specified use, it will be evaluated using additional standard tests in accordance with the expected use.)

Lille, 9th July 1997.

Le chef de laboratoire :

Mme. M. MAINGAIN.

Le directeur général :



M. Ch. LEPAGE.

ID212の殺菌性の証明

Laboratoire Midac 1997/09/17

Determination of the basic fongicidal activity of ID212

ID212はヨーロッパ規格EN1275に準した基本的な殺菌活性を有しています。

MIDAC LABORATOIRE

Etude, Conseil, Expertise et Formation en Microbiologie.

Test Report n ° **97 146 CEN-2.**

cofrac ESSAIS LABORATOIRE ACCRÉDITÉ SOUS LE N° 1-0019

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

Object : Determination of the basic fongicidal activity of
ID 212
(your ref. : 97.05.23 Fax)

L'accréditation par la Section Essais du COFRAC atteste uniquement de la compétence technique du laboratoire pour les essais ou analyses couverts par l'accréditation.

La reproduction de ce rapport d'essai n'est autorisée que sous forme de fac-similé photographique intégral.

Il comporte 4 pages et 0 annexe.

CONCLUSION :

In the specified operating conditions and for the sample under test, the product ID 212 (97.04.25 sample) has a basic fongicidal activity in accordance with the european standard NF EN 1275.

(To qualify the product as antiseptic and/or disinfectant for a specified use, it will be evaluated using additional standard tests in accordance with the expected use.)

Lille, 19th of september 1997.

Le chef de laboratoire :

Mme. M. MAINGAIN.

Le directeur général :

M. Ch. LEPAGE.

高有機負荷下でのID212の希釈液使用期間の判定

Dr.rer.Nat.K-M.Wolf and Dr.rer.Nat.D.Heermann 2006/11/27

Examination to determine the standing time of ID212 with high organic load(blood)

ID212の希釈液の使用期間はDGHMのガイドラインに沿って検証されました。2%の希釈液の場合、血液の汚染が2%を超えない限り、最長7日まで使用可能です。ただし、0.5%の血液の希釈液への混入は汚染と考えられます。そのため、出来るだけ早い時期に希釈液を交換することが推奨されます。

27.11.2006
WF

DÜRR SYSTEM-HYGIENE
ID 212
Instrument Disinfection

Examination to determine the standing time of ID 212 with high organic load (blood)

The time allowed for a disinfectant to stand over several days is gaining ever greater importance because of the increasingly problematic nature of waste disposal and the levels of pollution in waste waters. Prerequisite for the use of disinfectants over several days is a demonstration of the effectiveness under conditions similar to those in practice. In a publication by the Federal Health Department (PETERS, J. and G.SPICHER – Bundesgesundhbl. 34, 262 (1991)), it was proposed that the standing times for disinfectants be investigated under conditions similar to those in practice by polluting the disinfectant with e.g. 2% blood and contaminated test objects.

In order to determine a prolonged standing time, the effectiveness of ID 212 was tested with higher blood contaminations in a modified investigation under conditions similar to those in practice. It was performed in accordance with method 15 of the "DGHM standard methods for testing chemical disinfection procedures, effective 1st September 2001".

Assessment

As the test results have shown, the effectiveness of a 2% ready-to-use solution was retained over a test period of 14 days against the test bacteria Staphylococcus aureus, Enterococcus hirae, Pseudomona aeruginosa as well as the yeast Candida albicans in the tests under conditions similar to those in practice in spite of a high organic load of 2% blood. The test was a quantitative germ carrier test with high organic load. Pieces of frosted glass were used as germ carriers.

Taking a corresponding safety margin into consideration, a **standing time of max. 7 days of the 2% ID 212 ready-to-use solution** can be recommended provided that the contamination by blood does not exceed 2%.

As disinfectants are already soiled to a great extent by a contamination of 0.5% blood, it is recommended to replace the solution earlier on account of its appearance – irrespective of the possibly prolonged standing time.

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

Dr. rer. nat. D. Heermann

超音波洗浄機使用時にID212の効力に関する検証

Dr.rer.Nat.K-M.Wolf and Dr.rer.nat.D.Heermann 2009/03/09

Investigation into the activity of ID212 when using the ultrasonic cleaner

超音波洗浄機の使用により、ID212の作用時間を短縮することが証明されています。2%の希釈液は試験した黄色ブドウ球菌、エンテロッカス・ヒラエ、緑膿菌、そしてカンジダ・アルビカンスに対し2分以内で効力があることが判明されています。

DESINFEKTION · HYGIENE · FOTOCHEMIE

orochemie

09.03.2009
WF

DÜRR SYSTEM-HYGIENE
ID 212
Instrument Disinfection

Investigation into the activity of ID 212 when using the ultrasonic cleaner Dürr Hygosonic

The activity of ID 212 when used in ultrasonic equipment Dürr Hygosonic was tested under conditions similar to those in practice in accordance with method 15 of the "DGHM standard methods for testing chemical disinfection processes, effective 1st September 2001".

Evaluation

The results show that the required action time of the instrument disinfectant ID 212 could be reduced by using ultrasonic equipment. A 2% ID 212 ready-to-use solution was effective against the tested bacteria Staphylococcus aureus, Enterococcus hirae, Pseudomonas aeruginosa as well as the yeast Candida albicans within only 2 minutes. The quantitative germ carrier tests with high organic load were made under conditions similar to those in practice. Pieces of frosted glass were used as germ carriers.

The following recommendations for use are provided for reliable instrument disinfection with ID 212 when used in the ultrasonic cleaner Dürr Hygosonic:

2% at a contact time of 2 minutes

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

Dr. rer. nat. D. Heermann

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Sitz: 70806 Kornwestheim · Amtsgericht Stuttgart HRA 201527 · Persönlich haftende Gesellschaft: orochemie Verwaltungs-GmbH, HRB 200833 · Geschäftsführer: Martin Dürrstein, Christian Pflug · USt-ID: DE 146 146 522 · Steuer-Nr. 71378-20208 Finanzamt Ludwigsburg · BW Bank Stuttgart, Konto-Nr. 2 716 725, BLZ 600 501 01, S.W.I.F.T.-Adresse SOLADEST

超音波洗浄機使用時にID212の効力に関する検証

Dr.rer.Nat.K-M.Wolf and Dr.rer.nat.D.Heermann 2006/12/01
Investigation into the activity of ID212 when using the ultrasonic cleaner

超音波洗浄機の使用により、ID212の作用時間を短縮することが証明されています。2%の希釈液は試験した黄色ブドウ球菌、エンテロッカス・ヒラエ、緑膿菌、そしてカンジダ・アルビカンスに対し2分以内で効力があることが判明されています。

01.12.2006
WF

DÜRR SYSTEM-HYGIENE
ID 212
Instrument Disinfection

Investigation into the activity of ID 212 when using an ultrasonic cleaner

The activity of ID 212 when used in ultrasonic equipment (ELMA Transsonic 460/H) was tested under conditions similar to those in practice in accordance with method 15 of the "DGHM standard methods for testing chemical disinfection processes, effective 1st September 2001".

Evaluation

The results show that the required action time of the instrument disinfectant ID 212 could be reduced by using ultrasonic equipment. A 2% ID 212 ready-to-use solution was effective against the tested bacteria Staphylococcus aureus, Enterococcus hirae, Pseudomonas aeruginosa as well as the yeast Candida albicans within only 2 minutes. The quantitative germ carrier tests with high organic load were made under conditions similar to those in practice. Pieces of frosted glass were used as germ carriers.

The following recommendations for use are provided for reliable instrument disinfection with ID 212 when used in an ultrasonic cleaner:

2% at a **contact time** of **2 minutes**

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

Dr. rer. nat. D. Heermann

超音波洗浄機を用いた器具消毒のためのID212の適合性

Dr.H Brill Dr Brill+Partner GmbH 2007/10/11

Suitability of ID213 for instrument disinfection using ultrasound(Tuberculocidal effect according to DIN EN14563:2002)

ID213はprEN14563:2002に従い、マイコバクテリウム(結核菌）への効力を測る化学品による器具消毒の定量的キャリア試験が行なわれました。

結果、該当製品は濃度2．0%に対し60分の作用時間で規範の要求（RF≥4）を満たしています。

DR. RER. NAT. HOLGER BRILL

C/O DR. BRILL + PARTNER GMBH
LABOR FÜR HYGIENE UND MIKROBIOLOGIE
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DR. H. BRILL · C/O DR. BRILL + PARTNER GMBH · PAPENREYE 61 · 22453 HAMBURG

orochemie Hygiene Präparate GmbH + Co
Mr Dr. K.-M. Wolf
PO box 1630
D - 70798 Kornwestheim

Hamburg, 11 October 2007

Expert's report

Suitability of ***DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion***
for instrument disinfection using ultrasound
(tuberculocidal activity according to DIN EN 14563:2002)

The disinfectant ***DÜRR SYSTEM-HYGIENE ID 212 INSTRUMENTENDESINFEKTION*** was evaluated according to prEN 14563:2002 "Quantitative carrier test for the evaluation of mycobactericidal activity of chemical disinfectants for instruments used in the medical area – Test method and requirements (phase 2/step 2)".

According to test report no. L 07/027 from Dr. Brill + Partner GmbH, ***DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion*** showed a tuberculocidal activity under high organic load using ultrasound.

DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion fulfils the requirements of the norm (RF ≥ 4) by the following concentration-time relation:

2.0 % **60 minutes.**

Dr Holger Brill

ID212のワクシナウイルスへの効力

Dr.Jochen Steinmann 2003/03/07
vacciniavirus efficacy of ID212

BGAとDVVが定めるガイドラインに従い、ID212のワクシニアウイルスへの効力を定量的浮遊実験にて検証しました。結果、濃度2.0%に対し、1分の作用時間が推奨されています。

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

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2003-03-07
Dr. St/sbe

Mikrolab GmbH, Norderoog 2, D-28259 Bremen

orochemie
Postfach 16 30

70798 Kornwestheim

vacciniavirus efficacy of DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion

EXPERT'S INVESTIGATION REPORT

The virucidal efficacy of the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion from the firm orochemie against vacciniavirus strain Elstree was investigated by a quantitative suspension test published as a guideline of the Bundesgesundheitsamt (BGA, Federal Board of Health, now Robert Koch-Institut) and the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (DVV, German Society for the Control of Virus Diseases). According to this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having virucidal efficacy if within the recommended exposure period the titre is reduced by 4 $\log_{10}$.

DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion 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 instrument disinfectant DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion for the inactivation of vacciniavirus as follows:

2.0% 1 min.

Dr. J. Steinmann

ID212のウシウイルス性下痢ウイルス（BVDV)への効力

Dr.Jochen Steinmann 2003/03/07
BVDV efficacy of ID212

BFAとDVVが定めるガイドラインに従いID212のウシウイルス性下痢ウイルスへの効力が検証されました。（BVDV）はC型肝炎ウイルスの代理ウイルスとして選択され、濃度2.0%の時0.5分の作用時間が効果的であると証明されています。

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2002-08-12
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BVDV efficacy of DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion

EXPERT'S INVESTIGATION REPORT

The virucidal efficacy of the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion 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 ID 212 Instrumentendesinfektion was examined as a 2.0% and 4.0% 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 instrument disinfectant DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion for the inactivation of BVDV as follows:

2.0% **0.5 min.**

Dr. J. Steinmann

EN14476:2007-02に従い汚染条件下、20度での定量的浮遊実験におけるID212のMNVへの有効性

Dr.Jochen Steinmann 2008/09/30

Efficacy of ID212 against MNV in a quantitative suspension test at 20 dgree following EN14476:2007-02 under dirty conditions

EN14476:2007-02に従いID212のマウスノロウイルスへの効力を検証しました。結果、濃度4.0%に対し60分の作用時間が有効であると証明されています。

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30.09.2008
Dr. St/BB

MikroLab GmbH, Norderoog 2, D-28259 Bremen

orochemie GmbH + Co KG
Max-Planck-Straße 27

70798 Kornwestheim

Efficacy of DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion 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 08ML661M dating 30.09.2008.
The virus-inactivating properties of the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 212 Instrumentendesinfektion of orochemie 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 ID 212 Instrumentendesinfektion 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 60 minutes (4.0 %) virus reduction exceeded 4 $\log_{10}$-steps. Therefore, a virucidal activity under dirty conditions against MNV was measured as follows:

4.0 % **60 min**

Dr. J. Steinmann

フランス規格NF T 72 181のバクテリオファージMS2のスクリーリングテスト

Mrs.M.Maingain and M.Ch.Lepage 1997/09/10
Determination of virucidal activity of ID212
ID212を希釈して、殺菌効果もしくは消毒効果を検証しています。
試験結果の詳細は以下のテーブルに記載されています。

MIDAC LABORATOIRE
Etude, Conseil, Expertise et Formation en Microbiologie.

Test report **n ° 97 148 181 - 2.**

cofrac ESSAIS
LABORATOIRE ACCRÉDITÉ SOUS LE N° 1-0019

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

Object : Determination of virucidal activity of
ID 212
(your ref. : letter of 97.04.24)

L'accréditation par la Section Essais du COFRAC atteste uniquement de la compétence technique du laboratoire pour les essais ou analyses couverts par l'accréditation.

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Il comporte 3 pages et 0 annexe.

229 rue Solférino - 59000 LILLE-FRANCE - Tél. 03.20.60.07.09 - Télécopie 03.20.95.90.09

PRINCIPLE :

The determination of virucidal activity has been carried out in accordance with the method described in the offical french standart **NF T 72 181** : "Water miscible, antiseptics and disinfectants used in liquid form. Determination of virucidal activity - Bacteriophages - december 1989".

Only the strain of bacteriophage MS2 has been tested (screening).

IDENTIFICATION OF THE SAMPLE :

Name of the product : **ID 212 (sample of 97.04.25).**

Manufacter : **DÜRR DENTAL FRANCE.**

Date of delivery : 97.04.25

Storage conditions : Room temperature, in darkness.

Period of analysis : 97.06.23 to 97.09.05.

Diluent of product :

- Recommanded by the manufacter : water.
- Used during the tests : sterile distilled water.

TESTS CONDITIONS :

Expected reduction : 10^4 .
Contact : **15 minutes ± 30 seconds at 20°C ± 1°C.**

TEST RESULTS:

Validation tests : Neutralizing method : 1/50 dilution in LPT medium.

Tested concentrations in % (v/v) :	Strain :	N	N'	n	T	$\frac{N'}{N}$	$\frac{n}{N}$	$\frac{T}{N'}$
0,05	*MS2*	237,0	244,5	231,0	235,0	1,03	0,97	0,96

Experimental conditions are validated : $n/N > 0,5$ and $T/N' \geq 0,5$.

Actual test.

Strain :	Initial population PFU/ml :	x Concentrations in % (v/v) in contact with the virus : 0,25	0,5	1	2	3	pH conc. mini	maxi
MS 2	$227,0 \times 10^6$	CL	CL	< 500	< 500	< 500	7,2	7,6

CL : Confluent lysis.

CONCLUSION:

Under the specified conditions and for the sample of product under test, the **ID 212 (sample of 97.04.25) presents a virucidal activity** in accordance with the french standart **NF T72 181,** at the concentration of **0,01% (v/v)** when the reference strain is **bacteriophage *MS2*.**

Lille, 10th of September 1997.

Le chef de laboratoire : Le directeur général :

Mrs. M. MAINGAIN. M. Ch. LEPAGE.

ウィスターラットを用いたID212の急性経口毒性の検証

Dr.K.-M.Wolf Harlan Bioservice 2003/05/06
Acute Toxic Class Method with ID212 in Rat

3匹のオスとメスのラットを用いID212の急性経口毒性を14日間にわたり検証しました。2000mg/kgをそれぞれ経口にて与えた結果、1匹のオスは4日後に死亡し、残りの2匹のオスとメスのラットには死亡は観察されませんでした。また14日目の肉眼的病理検査においても、いかなる所見も見受けられませんでした。結果ID212は毒性無しと判定されています。

Harlan
BIOSERVICE
FOR SCIENCE

Final Report

ACUTE ORAL TOXICITY
Acute Toxic Class Method with

"DÜRR SYSTEM-HYGIENE

ID 212 - Instrumentendesinfektion"

in the Rat

Study No.: **10-4-0111-03**

Sponsor: **orochemie**
Hygiene Präparate GmbH + Co
Forschungs- und Entwicklungs-KG
Max-Planck-Straße 27
D-70806 Kornwestheim

Harlan BIOSERVICE FOR SCIENCE

Contents

Harlan
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Harlan BIOSERVICE FOR SCIENCE

General Statements

Study Title:	Acute Oral Toxicity Acute Toxic Class Method with **"DÜRR SYSTEM-HYGIENE** **ID 212 - Instrumentendesinfektion"** in the Rat
Study Number:	10-4-0111-03
Sponsor:	**orochemie** Hygiene Präparate GmbH + Co Forschungs- und Entwicklungs-KG Max-Planck-Straße 27 D-70806 Kornwestheim
Contact Person:	**Dr. K.-M. Wolf** Tel.: 07154 / 13 08-0
Testing Facility:	***Harlan* Bioservice for Science GmbH** Südkampen Nr. 31 29664 Walsrode

Study Schedule

Dates of Study Protocol:	18 February 2003 (Study Director) 28 February 2003 (Sponsor)
Start Date:	31 March 2003
Completion of Experimental Phase:	16 April 2003
Date of Final Report:	6 May 2003

Harlan
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FOR SCIENCE

Declaration

The undersigned hereby declares that the work was performed under her supervision and 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 her 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.

GLP Compliance

To the best of my knowledge, this study was performed in accordance with the principles of Good Laboratory Practice for the testing of chemicals as specified by national (German Chemicals Law, Annex 1, 20 June 2002) and international (OECD, Paris, 1998; Directive 99/11/EEC, 8 May 1999) legislation.

C. Bien

PD Dr. Erika Bien
Study Director

6/5/2003

Date

Harlan
BIOSERVICE
FOR SCIENCE

1.0 Summary

The acute oral toxicity of **"DÜRR SYSTEM-HYGIENE ID 212 - Instrumentendesinfektion"** was investigated according to the ATC method in one step using 3 male and 3 female rats.
Three female animals were given a single oral administration of the test article **"DÜRR SYSTEM-HYGIENE ID 212 - Instrumentendesinfektion"** at a dose of 2000 mg/kg. Since no female animal died after the administration, the test was continued using three male animals which were treated in the same way with a single oral dose of **"DÜRR SYSTEM-HYGIENE ID 212 - Instrumentendesinfektion"** at 2000 mg/kg. One male animal died prematurely at day 4 after treatment.
Clinical observations were carried out at regular intervals during the 14-day observation period. Body weights were determined immediately before treatment and on days 7 and 14 p.a.
Gross pathological examinations were carried out immediately at termination on all surviving animals.

The following results were obtained:

- One out of three male rats died at day 4 after treatment following the dose of 2000 mg/kg. There was no further mortality during the course of the subsequent 14-day observation period. No female animal died following the dose of 2000 mg/kg.
- Clinical signs such as reduced activity, paleness, reduced respiratory rate and breathing sounds were observed in the prematurely deceased male animal on the days before death. There were no clinical signs in the two other males and in all females.
- With the exception of one female animal, there was no influence of the treatment on the body weight development in the surviving male and female animals during the 14-day observation period.
- There were some macroscopic findings in the animal which died prematurely. Gross pathological examinations in surviving animals on day 14 p.a. did not reveal any findings.

According to the EEC Directive 2001/59, 6 August 2001 and the Gefahrstoffverordnung (GefStoffV) of 15 November 1999 (BGBl. I, p. 2233), the test article **"DÜRR SYSTEM-HYGIENE ID 212 - Instrumentendesinfektion"** is classified as

"non toxic",

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

ウィスターラットを用いたID212の急性経口毒性の検証

IBR Forschungs GmbH 1987/05/22

The result of testing the acute oral toxicity in rats in conformity with the OECD guidelines

ID212が一回の経口投与後にラットに毒性作用を引き起こすか検証するために試験を行いました。また中程度の致死量は14日間にわたり観察されました。結果ID212は毒性が低いと判定されています。

I B R Forschungs GmbH
(Research Laboratories)

Südkampen Nr. 31
Tel.: (05166) 50 66
D-3030 Walsrode 1

22nd May 1987

Project No. 1-4-334-87

DÜRR SYSTEM-HYGIENE
ID 212
Instrument Disinfection

Expertise

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

I. TEST OBJECTIVE

The test was carried out in order to establish whether the test substance ID 212 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, 1987, 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, salivation, diarrhoea, 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 reddening of the small intestine's mucous membrane. 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 + 14 days	ml/kg	mg/kg
male	4.71	4982
female	3.72 (3.12 - 5.61)	3936 (3292 - 5926)
male + female	4.13 (3.71 - 5.32)	4360 (3918 - 5618)

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)

ID212の原料適合性の試験

Dr.rer.nat.K.-M.Wolf and Dr.rer.nat.D.Heermann 1993/10/27
The Result of Testing the material compatibility of ID212

ID212の外科用器具または歯科用器具とアルミニウムトレイとの材料適合性を検証するために行われました。ID212の2%の希釈液に器具を室温の部屋で浸漬し、4週間検証しました。毎朝、器具を希釈液から取り出し、水で濯がずに自然乾燥させ、再び浸漬を繰り返しました。この検証後、器具を水ですすぎ乾燥させた後に、実態顕微鏡で検査しました。結果、目に見える変化は器具に認められませんでした。すなわち、ID212は外科用器具または歯科用器具に対する優れた適合性を保有することが証明されます。

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DÜRR SYSTEM-HYGIENE

ID 212
Instrument Disinfection

Expertise
on the results of testing the material compatibility of ID 212

The aim of the test was to determine the material compatibility of ID 212 with general and surgical instrumentarium as well as rotary dental instrumentarium and aluminium trays.

1. **General and surgical dental instrumentarium**
The instruments were immerged into a 2 % use solution of ID 212 in an instrument container at room temperature. Test duration was 4 weeks. Every other day, the instruments were removed from the solution in the mornings - without rinsing them with water - and left in the air. Subsequently, the instruments were placed into the solution again. At the end of the tests, the instruments were rinsed with water, thoroughly dried and examined under a stereomicroscope.

Results
No visible changes were detected with the different instruments (see table 1). On the basis of these results, ID 212 produced an excellent material compatibility with the general and surgical dental instrumentarium.

2. **Rotary dental instrumentarium**
The rotary instruments were immerged into a 2 % use solution of ID 212 at room temperature.Test duration was 14 days. The instruments were removed from the solution every morning, left in the air without rinsing and placed into the solution again in the evenings. Upon termination of the tests, all drills, root canal instuments and polishers etc. were rinsed with water and thoroughly dried, followed by a visual and stereomicroscopic evaluation.

Results
According to the results shown in table 2, no material changes occurred after the immersion of the different rotary instruments into the ID 212 solution. Just the root canal instruments with an aluminium head, after one day's test duration, showed slight blooms which, however, do not impair the utility value.

3. **Aluminium trays of Messrs. Svenska Dental**
Differently coloured aluminium trays were placed into a 2 % use solution of ID 212 for 14 days.

Results
The immersion resulted in no material changes whatsoever, especially the colours were neither affected nor did they peel off. An excellent material compatibility of ID 212 with aluminium trayscan be assessed.

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

(Dr. rer. nat. D. Heermann)

濃度2%のID212溶液を使用する場合の消毒液残留物の検証

Dr.rer.nat.K.-M.Wolf and Dipl.Ing.Peter Brauner 2006/01/13
Test for Residues on Instruments when Using a 2% ID212 Solution

この試験は、歯科用器具、例えばプローブ、ミラー、ピンセット、レバー、スパチュラなどを濃度2%のID212に浸漬除菌した際の、残留物の判定をするために行われました。結果、700gの器具を3リットルの水でよくすすぎ、消毒剤残留物を器具から除去するだけで十分効果的であることが証明されています。

DESINFEKTION · HYGIENE · FOTOCHEMIE

orochemie

13 January 2006
WF/DW

DÜRR SYSTEM-HYGIENE ID 212 Instrument Disinfection
Test for Residues on Instruments when Using a 2% ID 212 Solution

It was the objective of the test to determine residues of ID 212 which has been used in the form of a 2% ready-to-use solution on dental instruments, e.g. probes, mirrors, tweezers, levers, mixing spatulas, etc. and to give recommendations for rinsing the instruments with water.

ID 212 is an aqueous disinfectant concentrate. To make a 2% ready-to-use solution for example, fill 20 ml of ID 212 up to 1 litre with water. Due to the good water solubility of the ingredients of ID 212, the tests were based on the assumption that residues of the ingredients of ID 212 cannot be found on disinfected instruments when the ingredients cannot be detected in the rinsing liquid.

Experimental Procedure:

Two litres of a 2% ready-to-use solution of ID 212 (Ch.-B. 21116) were poured into a container (fraise) with tray and charged with instruments, e.g. mirrors, probes, tweezers, mixing spatulas, levers, etc. (700 g).

The tray with the instruments was taken out of the solution after an exposure time of 1 minute. The instruments were left to drain for 30 seconds and then put into another container with 1 l water. The tray with the instruments was taken out after 30 seconds and left to drain for 30 seconds. A sample was withdrawn from the rinsing solution. The rest of the rinsing solution was rejected, the container was rinsed and dried. Afterwards, the rinsing procedure with water was repeated three times in the second container.

The quaternary ammonium compound alkyl-benzyl-dimethyl-ammonium chloride was analytically determined to determine the residues of the disinfectant in the solution and on the instruments, respectively.

Test Results:

As the test results show, it is sufficient to rinse 700 g of instruments with in all 3 litres of water to remove all disinfectant residues from the instruments (see enclosure).

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Assessment and Recommendations for Use:

As the test results show, all residues of a 2% ready-to-use solution of ID 212 were removed from the solution and thus from the instruments by rinsing them with in all 3 litres of water.

The following recommendation for use can be given for the practice: Rinse instruments in a container with tray with 3 to 5 litres of water for approx. 15 to 20 seconds. To avoid stains when sterilizing the instruments, rinse them with demineralised water.

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