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

ID220 rotary instrument disinfection

バー／リーマー｜回転器具の除菌

2019年6月現在

DÜRR DENTAL

個別診断／試験結果／効能証明書
ID220 rotary instrument disinfection
バー／リーマー｜回転器具の除菌

ID220の汚染状況下における菌及び真菌（C.アルビカンス）への有効性検証

Prof. Dr. Med. H. - P. Werner 2005/03/08

ID220 Instrument disinfection, Bactericidal and fungicidal (C. albicans) efficacy, Dirty condition

ドイツ応用衛生協会（DGHM）の基準に従い、汚染状況下における定量的浮遊実験と診療を想定した実使用試験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌、C.アルビカンスに対して行った結果、ID220（100%濃度/未希釈）は汚染状況下で1分間の作用時間で十分な有効性を示し、以上の試験結果はVAH消毒委員会による消毒プロセスの認証の評価基準を満たしていることが実証された。

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2005-03-08

DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion
Instrument disinfection
Bactericidal and fungicidal (C. albicans) efficacy
Dirty condition

EXPERTISE

After testing the disinfectant **DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion** in accordance with the

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

I give the following evaluation of the results from the test report 2005-03-08 (SN 4025):

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 test were carried out under **dirty condion** and spread plate technique for germ detection.
DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion resulted in sufficient reduction (5 lg. Units of the test bacteria S. aureus, E. hirae and P. aeruginosa or 4 lg. units of C. albicans) under dirty condition

in 75 %	within	30 seconds and
in 50 %	within	1 minute.

Results under practical conditions

The efficacy of the diesinfectant **DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion** was tested under **dirty condition**.

Under this condition in

75 % within 1 minute

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

Application recommendations for
DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion
For instrument disinfection

According to the results abtained **DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion** complies with the

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

Under **dirty condition** against S. aureus, E. hirae, P. aeruginosa and C. albicans

concentrated within 1 minute.

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

ID220の汚染状況下における真菌（アスペルギルスニガー）への有効性検証

PD Dr. med. H.-P. Werner 2005/10/18

ID220 Instrument disinfection, Fungicidal efficacy against Aspergillus niger, Dirty condition

DGHMのガイドラインに従い、汚染状況下における定量的浮遊実験と診療を想定した実使用試験をアスペルギウスニガーに対して行った結果、ID220（100%濃度/未希釈）は30秒の作用時間で十分な有効性を示し、以上の試験結果はVAH消毒委員会による消毒プロセスの認証の評価基準を満たしていることが実証された。

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2005-10-18

DÜRR SYSTEM HYGIENE ID 220 Bohrerdesinfektion
Instrument disinfection
Fungicidal efficacy against Aspergillus niger
Dirty condition

EXPERTISE

After testing the disinfectant **DÜRR SYSTEM HYGIENE ID 220 Bohrerdesinfektion** accordance with the

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

I give the following evaluation of the results from the test report 2005-10-17 (SN 4025):

Results of the in vitro-tests

The quantitative suspension test were carried out under **dirty conditions.** **DÜRR SYSTEM HYGIENE ID 220 Bohrerdesinfektion** resulted in sufficient reduction (4 lg. units of the test strain A. niger) under **dirty condition**

in 90 % within 30 seconds.

Ergebnisse under practical conditions

The efficacy of the disinfectants **DÜRR SYSTEM HYGIENE ID 220 Bohrerdesinfektion** was tested under dirty condition.

Under this condition in

100 % within 30 seconds

a sufficient efficacy against A. niger.

Application recommendations for
DÜRR SYSTEM HYGIENE ID 220 Bohrerdesinfektion
for instrument disinfection

According to the results abtained **DÜRR SYSTEM HYGIENE ID 220 Bohrerdesinfektion** complies with the

„Requirements Specification fort he Admission of Chemical Disinfection Processes in the disinfection commission of VAH".

under **dirty condition** against **A. niger**

concentrated within 30 seconds.

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

ID220の汚染状況下における結核菌への有効性検証

PD Dr. med. H.-P. Werner 2005/10/18

ID220 Instrument disinfection, Tuberculocidal efficacy, Dirty condition

DGHMのガイドラインに従い、汚染状況下における定量的浮遊実験と診療を想定した実使用試験を結核菌に対して行った結果、ID220（100%濃度/未希釈）は1分の作用時間で十分な有効性を示し、以上の試験結果はVAH消毒委員会による消毒プロセスの認証の評価基準を満たしていることが実証された。

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18.10.2005

DÜRR SYSTEM HYGIENE ID 220 Bohrerdesinfektion
Instrument disinfection
Tuberculocidal efficacy
Dirty condition

EXPERTISE

After testing the disinfectant **DÜRR SYSTEM HYGIENE ID 220 Bohrerdesinfektion** accordance with the

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

I give the following evaluation of the results from the test report 2005-10-17 (SN 4025):

Results of the in vitro-tests

The quantitative suspension test were carried out under **dirty conditions.** **DÜRR SYSTEM HYGIENE ID 220 Bohrerdesinfektion** resulted in sufficient reduction (4 lg. units of the test strain M. terrae) under **dirty condition**

in 90 % within 1 minute.

Ergebnisse underr practical conditions

The efficacy of the disinfectants **DÜRR SYSTEM HYGIENE ID 220 Bohrerdesinfektion** was tested under dirty condition.

Under this condition in

100 % within 30 seconds

A sufficient efficacy against M. terrae.

Application recommendations for
DÜRR SYSTEM HYGIENE ID 220 Bohrerdesinfektion
for instrument disinfection

According to the results abtained **DÜRR SYSTEM HYGIENE ID 220 Bohrerdesinfektion** complies with the

„Requirements Specification fort he Admission of Chemical Disinfection Processes in the disinfection commission of VAH“

under **dirty condition** against M. terrae

concentrated within 1 minute.

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

DGHMに準じたID220の化学的消毒薬としての有効性検証試験

Dr. Holger. Brill 2005/06/30

Summary of the test carried out in accordance with the standard methods of the DGHM

DGHMの基準に従いID220の菌・真菌（アスペルギルスニガー）及び結核菌（マイコバクテリウム）への静菌性・殺菌性効果を検証した結果、ID220（100%濃度/未希釈）は菌・真菌・結核菌に対し1分の作用時間で十分な有効性を示すことが証明された。

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Hamburg, 30 June 2005

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

The instrument disinfectant ***DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION*** 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 bacteriostatic and fungistatic as well as bactericidal and fungicidal. In addition, the test preparation is tuberculocidal, as it is effective against *Mycobacterium terrae*. Furthermore, the test preparation has a very good effectiveness against the mould *Aspergillus niger*.

The use-recommendation for ***DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION*** for chemical instrument disinfection including *Mycobacterium terrae* is:

100 % 1 minute

Dr. Holger Brill

ID220の定量的浮遊試験における殺菌性検証

HygCen, Dr. med. H.-P. Werner and Kathrin Naujox 2005/02/09
Quantitative Suspension test for the evaluation of bactericidal efficacy

EN13727に準じて、ID220の汚染状況下における定量的浮遊実験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌に対して行った結果、有効成分1-プロパノール15g／100g及び水酸化カリウム／100g含有のID220（80%濃度／1.25倍希釈）は汚染状況下（0.3%アルブミン+0.3%ヒツジ赤血球）において、30秒間の作用時間で十分な有効性を示した。

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2005-02-09
Prof. We/ku

DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion
Quantitative suspension test
DIN EN 13727 (march 2004)– bactericidal efficacy
(phase 2, step 1)

TEST REPORT

Identification of the test laboratory:	SN 4025
Test product:	DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion
Batch number :	25133 (WF-022)
Manufacturer:	orochemie
Date of order:	2004-08-11
Date of delivery:	2004-08-16
Appearance:	clear, light blue liquid
Odour:	alcoholic, aromatic
Active substances per 100 g:	15 g 1-Propanol Kaliumhydroxid

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Conclusion: According to DIN EN 13727 (03/2004) the batch 25133 of the product DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion possesses a bactericidal activity under dirty conditions (0.3 % albumine + 0.3 % sheep-erythrocytes) in 30 seconds for the referenced strains *Staphylococcus aureus*, *Enterococcus hirae* and *Pseudomonas aeruginosa* when diluted at 80 % (v/v) in distilled water.

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

HygCen
Centrum für Hygiene und
medizinische Produktsicherheit GmbH

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

CENTRUM FÜR HYGIENE UND MEDIZINISCHE PRODUKTSICHERHEIT GMBH HYGCEN

K. Naujox
Department manager

ID220の殺菌効力の検証

Dr. Holger Brill 2005/10/01

Verification of the bactericidal effect of ID220 according to EN13727

EN13727に準じて、ID220の汚染状況下における黄色ブドウ球菌、腸内連鎖球菌、緑膿菌への殺菌性効果を検証した結果、ID220（100%濃度／未希釈）は汚染状況下（0.3%ヒツジ赤血球+0.3%牛アルブミン）において、1分の作用時間で十分な有効性を示した。

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Verification of the bactericidal effect of ***DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION*** according to EN 13727: 2004 (phase 2, step 1)

Expert's report

In accordance with EN 13727 (2004), the test report no. L 04/228.1 of Dr. Brill + Partner GmbH shows that batch no. 25156 of the product ***„DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION"*** has in dilution with hard water under high organic load (3 g/L sheep erythrocytes + 3 g/l bovine albumin) a bactericidal effect against the test germs *Staphylococcus aureus*, *Enterococcus hirae* and *Pseudomonas aeruginosa*. The following concentration-time relationship proved to be sufficiently effective:

100 % **1 minute**

Hamburg, 01.10.2005

Dr. Holger Brill

ID220の定量的浮遊試験における殺真菌性評価

HygCen, Dr. med. H.-P. Werner and Kathrin Naujox 2005/02/15
Quantitative Suspension test for the evaluation of fungicidal activity

EN13624に準じて、ID220の希釈中和法を用いた殺真菌力評価のために、定量的浮遊試験をカンジダ・アルビカンス及びアスペルギルスニガーに対して行った結果、20℃の汚染状況下において有効成分1-プロパノール15g／100g及び水酸化カリウム／100g含有のID220（80%濃度／1.25倍希釈）は汚染状況下（0.3%アルブミン+0.3%ヒツジ赤血球）において30秒の作用時間で十分な有効性を示した。

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2005-02-15
Prof. We/ku

DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion
DIN EN 13624 (February 2004)
Quantitative suspension test for evaluation of fungicidal activity
(phase 2, step 1)

TEST REPORT

Test product:	DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion
Identification of the test laboratory:	SN 4025
Date of delivery:	2004-08-16
Batch number :	25133 (WF-022)
Manufacturer:	orochemie
Storage conditions:	those of the manufacturer
Active substances per 100 g:	15 g 1-Propanol Kaliumhydroxid
Appearance:	clear, light blue fluid
Odour:	alcoholic

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Conclusion: According to DIN EN 13624 (February 2004) the batch 25133 of product DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion possesses a fungicidal activity at 20 °C under dirty conditions (0.3 % albumine + 0.3 % sheep-erythrocytes) in 30 seconds for the referenced strains *Candida albicans* and *Aspergillus niger* when diluted at 80 % (v/v) in distilled water.

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

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K. Naujox
Department manager

ID220の汚染状況下における殺真菌効力の検証

Dr. Holger Brill 2005/10/10

Verification of the fungicidal effect of ID220 according to EN13624

EN13624に準じて、ID220の汚染状況下におけるカンジダ・アルビカンス及びアスペルギルス・ニガーへの殺真菌性効果を検証した結果、ID220（100%濃度／未希釈）は汚染状況下（0.3%ヒツジ赤血球+0.3%牛アルブミン）において、1分の作用時間で十分な有効性を示した。

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Verification of the fungicidal effect of ***DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION*** according to EN 13624: 2004 (phase 2, step 1)

Expert's report

In accordance with EN 13624 (2004), the test report no. L 04/228.2 from Dr. Brill + Partner GmbH shows that batch no. 25156 of the product „***DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION***" has in dilution with hard water under high organic load (3 g/L sheep erythrocytes + 3 g/l bovine albumin) a fungicidal effect against the tested germs *Candida albicans* and *Aspergillus niger*. The following concentration-time relationship proved to be sufficiently effective:

100 % **1 minute**

Hamburg, 10.10.2005

Dr. Holger Brill

ID220の定量的浮遊試験における殺結核菌性評価

HygCen, Dr. med. H.-P. Werner and Kathrin Naujox 2005/02/15
ID220-tuberculocidal efficacy

ID220の殺結核菌力評価のために、EN14348に準じて定量的浮遊試験をマイコバクテリウム・テラエに対して行った結果、有効成分1-プロパノール15g／100g及び水酸化カリウム／100g含有のID220（80%濃度／1.25倍希釈）は5分の作用時間で十分な有効性を示した。

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2005-02-15
Prof. We/ku

DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion
prEN 14348 – tuberculocidal efficacy
phase 2, step 1

TEST REPORT

Identification of the test laboratory:	SN 4025
Test product:	DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion
Batch no.:	25133 (WF-022)
Manufacturer:	orochemie
Date of order:	2004-08-11
Date of delivery:	2004-08-16
Storage conditions:	those of the manufacturer
Appearance:	clear, light blue fluid
Odour:	alcoholic, aromatic
Active substances per 100 g:	15 g 1-Propanol Kaliumhydroxid

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Conclusion:

According to prEN 14348 (09/2002), the product DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion possesses a tuberculocidal activity under dirty conditions (0.3 % albumine + 0.3 % sheep-erythrocytes) for the referenced strain *Mycobacterium terrae* in 5 minutes when diluted at 80 % (v/v) in distilled water.

Archive:

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

HygCen
Centrum für Hygiene und
medizinische Produktsicherheit GmbH

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

ZENTRUM FÜR HYGIENE UND MEDIZINISCHE PRODUKTSICHERHEIT GMBH HYGI CEN

Kathrin Naujox
Department manager

ID220の汚染状況下におけるマイコバクテリア殺菌効力の検証

Dr. Holger Brill 2005/10/10

Verification of the mycobactericidal effect of ID220 according to EN14348

EN14348に準じて、ID220の汚染状況下における殺結核菌性を検証するため、マイコバクテリウム・テラエ及びマイコバクテリウム・アビウムに対して試験を行った結果、ID220（100%濃度／未希釈）は汚染状況下（0.3%ヒツジ赤血球+0.3%牛アルブミン）において、1分の作用時間で十分な有効性を示した。

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Verification of the mycobactericidal effect of ***DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION*** according to EN 14348: 2005 (phase 2, step 1)

Expert's report

In accordance with EN 14348 (2005), the test report no. L 04/228.3 shows that batch no. 25156 of the product ***„DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION"*** has in dilution with hard water under high organic load (3 g/L sheep erythrocytes + 3 g/l bovine albumin) a mycobactericidal effect against the test germs *Mycobacterium avium* and *Mycobacterium terrae*. The following concentration-time relationship proved to be sufficiently effective:

100 % **1 minute**

Hamburg, 10.10.2005

Dr. Holger Brill

ID220の浸漬試験における殺菌効能検証

HygCen, Dr. med. H.-P. Werner and Kathrin Naujox 2005/03/11
Quantitative carrier test- bactericidal activity of chemical disinfectants for instruments

ID220の殺菌効能検証のために、EN14561に準じて浸漬試験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌に対して行った結果、20℃の汚染状況下（0.3%牛アルブミン+0.3%ヒツジ赤血球）において、有効成分1-プロパノール15g／100g及び水酸化カリウム／100g 含有のID220（75%濃度/約1.3倍希釈）は30秒間の作用時間で十分な有効性を示した。

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und Medizinprodukten
ZLG-P-715.98.13

2005-03-11
Prof. We/ku

DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion
Quantitative carrier test – bactericidal activity of chemical disinfectans for instruments -prEN 14561 (Nov. 2002)
(phase 2, Stepp 2)

TESTREPORT

Identification of the test laboratory.:	SN 4025
Manufacturer:	Orochemie GmbH
Test product:	DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion
Batch number.:	Ch.-B.: 25133 (WF-022)
Date of order:	2004-08-11
Date of delivery:	2004-08-16
Time of test:	2005-01-28 – 2005-01-30
Active substances in 100g:	15 g 1-Propanol Kaliumhydroxid
Appearance:	clear, blue liquid
Odour:	alcoholic
pH-values:	conc.: 13,74 75% in WSH: 13,59

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Conclusion: According to prEN 14561 (11/2002) the batch Ch.-B.: 25133 of product DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion under dirty condition (0,3 % bovine albumin + 0,3 % sheep erythrozytes) in 20 °C in 30 seconds after dillution of 75 % (v/v) in water of standardized hardness possesses a bactericidal activity against the test organsims *Staphylococcus aureus*, *Enterococcus hirae* and *Pseudomonas aeruginosa.*

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

Information: The test results are valid fort he named test subject only.
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Prof. Dr. med. H.-P. Werner
Manager of technical affairs

Kathrin Naujox
Department manager

ID220の汚染状況下における殺菌効力の検証

Dr. Holger Brill 2005/10/05

Verification of the bactericidal effect of ID220 according to EN14561

EN14561に準じて、ID220の汚染状況下における黄色ブドウ球菌、腸内連鎖球菌、緑膿菌への殺菌性効果を検証した結果、ID220（100%濃度／未希釈）は汚染状況下（0.3%ヒツジ赤血球+0.3%牛アルブミン）において、1分の作用時間で十分な有効性を示した。

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Verification of the bactericidal effect of ***DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION*** according to EN 14561: 2005 (phase 2, step 2)

Expert's report

In accordance with EN 14561 (2005), the test report no. L 04/228.4 from Dr. Brill + Partner GmbH shows that batch no. 25156 of the product ***„DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION"*** has in dilution with hard water under high organic load (3 g/L sheep erythrocytes + 3 g/l bovine albumin) a bactericidal effect against the tested germs *Staphylococcus aureus*, *Enterococcus hirae* and *Pseudomonas aeruginosa*. The following concentration-time relationship proved to be sufficiently effective:

100 % **1 minute**

Hamburg, 05.10.2005

Dr. Holger Brill

ID220の浸漬試験における殺真菌効能検証

HygCen, Dr. med. H.-P. Werner and Kathrin Naujox 2005/03/11
Quantitative carrier test- fungicidal activity of chemical disinfectants for instruments

ID220の殺真菌効能検証のために、EN14562に準じて浸漬試験をカンジダ・アルビカンス及びアスペルギルス・ニガーに対して行った結果、20℃の汚染状況下（0.3%牛アルブミン+0.3%ヒツジ赤血球）において、有効成分1-プロパノール15g／100g及び水酸化カリウム／100g 含有のID220（100%濃度/未希釈）は30秒間の作用時間で十分な有効性を示した。

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2005-03-11
Prof. We/ku

DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion
Quantitative carrier test – fungicidal activity of chemical disinfectants for Instruments prEN 14562 (Nov. 2002)
(pase 2, step 2

TESTREPORT

Identification of the test laboratory.:	SN 4025
Manufacturer:	Orochemie GmbH
Test product:	DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion
Batch number.:	Ch.-B.: 25133 (WF-022)
Date of order:	2004-08-11
Date of delivery:	2004-08-16
Time of test:	2005-01-27 – 2005-01-31
Active substances in 100g:	15 g 1-Propanol Kaliumhydroxid
Appearance:	clear, blue liquid
Odour:	alcoholic
pH-values:	conc.: 13,74 75% in WSH: 13,59

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Conclusion: According prEN 14562 (11/2002) the batch Ch.-B.: 25133 of product DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion under dirty condition (0,3 % bovine albumin + 0,3 % sheep erythrozytes) by 20 °C as concentrate in 30 seconds possisses an insufficient fungicidal activity against the test organisms *Candida albicans* and *Aspergillus niger*.

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

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

HygCen
Centrum für Hygiene und
med. Produktsicherheit GmbH

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

Kathrin Naujox
Department manager

ID220の汚染状況下における殺真菌効力の検証

Dr. Holger Brill 2005/10/05

Verification of the fungicidal effect of ID220 according to EN14562

EN14562に準じて、ID220の汚染状況下におけるカンジダ・アルビカンス及びアスペルギルス・ニガーへの殺真菌性効果を検証した結果、ID220（100%濃度／未希釈）は汚染状況下（0.3%ヒツジ赤血球+0.3%牛アルブミン）において、1分の作用時間で十分な有効性を示した。

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Verification of the fungicidal effect of ***DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION*** according to EN 14562: 2005 (phase 2, step 2)

Expert's report

In accordance with EN 14562 (2005), the test report no. L 04/228.5 from Dr. Brill + Partner GmbH shows that batch no. 25156 of the product ***„DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION"*** has in dilution with hard water under high organic load (3 g/L sheep erythrocytes + 3 g/l bovine albumin) a fungicidal effect against the tested germs *Candida albicans* and *Aspergillus niger*. The following concentration-time relationship proved to be sufficiently effective:

100 % **1 minute**

Hamburg, 05.10.2005

Dr. Holger Brill

ID220の浸漬試験における殺結核菌効能検証

HygCen, Dr. med. H.-P. Werner and Kathrin Naujox 2005/08/24
Quantitative carrier test-tuberculocidal activity

ID220の殺結核菌効能検証のために、EN14563に準じて浸漬試験をマイコバクテリウム・テラエに対して行った結果、汚染状況下（0.3%牛アルブミン+0.3%ヒツジ赤血球）において、有効成分1-プロパノール15g／100g及び水酸化カリウム／100g含有のID220（100%濃度/未希釈）は30秒間の作用時間で十分な有効性を示した。

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2005-08-24
Prof. We/ku

DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion
quantitative carrier test
prEN 14563 – tuberculocidal activity
(phase 2, step 2)

TESTREPORT

Identification of the test laboratory:	SN 4025
Test product	DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion
Batch number	25133 (WF-022)
Manufacturer:	orochemie
Date of order:	2004-08-11
Date of delivery:	2004-08-16
Storage conditions:	Those of the manufacturer
Product diluent recommended by the manufacturer for use:	concentrate
Appearance:	clear, blue liquid
Odour:	alcoholic
Active substances per 100 g:	15 g 1-Propanol Kaliumhydroxid

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Conclusion: According to prEN 14563 (11/2002) the bath 25133 (WF-022) of product DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion possesses a tuberculocidal activity under dirty conditions (0,3 % bovine albumin + 0,3 % sheep erythrozytes) in 30 seconds as concentrate against *Mycobacterium terrae.*

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

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

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

Kathrin Naujox
Department manager

ID220の汚染状況下における殺結核菌効力の検証

Dr. Holger Brill 2005/10/05

Verification of the mycobactericidal effect of ID220 according to EN14563

EN14563に準じて、ID220の汚染状況下におけるマイコバクテリウム・アビウム及びマイコバクテリウム・テラエへの殺結核菌性効果を検証した結果、ID220（100%濃度／未希釈）は汚染状況下（0.3%ヒツジ赤血球+0.3%牛アルブミン）において、1分の作用時間で十分な有効性を示した。

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Verification of the mycobactericidal effect of ***DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION*** according to EN 14563: 2005 (phase 2, step 2)

Expert's report

In accordance with EN 14563 (2005), the test report no. L 04/228.6 from Dr. Brill + Partner GmbH shows that batch no. 25156 of the product „***DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION***" has in dilution with hard water under high organic load (3 g/L sheep erythrocytes + 3 g/l bovine albumin) a bactericidal effect against the tested germs *Mycobacterium avium* and *Mycobacterium terrae*. The following concentration-time relationship proved to be sufficiently effective:

100 % **1 minute**

Hamburg, 05.10.2005

Dr. Holger Brill

ID220の殺菌効力の検証

Helsinki University Institute for Public Health, Dr. Juhani Ojajaervi 1987/04/09
On the results of testing the disinfecting strength of the ID220 disinfectant

歯科領域器具の消毒液ID220の有効殺菌成分である1%以下の水酸化カリウムの清潔環境下及び有機物の存在下における殺菌効力を検証するため、黄色ブドウ球菌、腸内連鎖球菌、緑膿菌の細菌細胞の懸濁液と混ぜた2%酵母を有機物とし、約300ppmの標準硬度の水（WHO規格）でKelsey法（有効濃度推定試験）を用いて室内温度にて以下の方法で試験を行った。細菌混濁液1mlを3mlのID220（100%濃度／未希釈）に添加し、8分後に細菌がまだ存在するか確認、さらに2分後別のサンプルとして細菌混濁液を添加し、再び8分後に細菌の有無を検証、同じ工程を3回目も繰り返し、それぞれのテスト液における細菌の増殖率を記録した。その結果、ID220（100%濃度／未希釈）は清潔環境下及び有機物存在下において十分な殺菌効力を示した。

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April 9, 1987

DÜRR SYSTEM-HYGIENE
ID 220
Disinfection of instruments

Expertise
on the results of testing the disinfecting strength of the ID 220 disinfectant

The substance to be examined was the ID 220 disinfectant (manufactured by Dürr System-Hygiene). According to the manufacturers, its active disinfecting ingredient is less than 1% of potassium hydroxide. The product is intended for the disinfection of instruments used in dental care.

The purpose of the examination 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 product was examined in an undiluted form.

Results

The results are shown in the attached Table. The product, in its undiluted form, killed the bacteria examined both in a clean environment and in the presence of an organic substance.

Enclosure: 1 Table

Helsinki, 9th April 1987.

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

ID220の有機物（血液）負荷状況下における使用可能期間の検証

Dr. rer. Nat. K.-M. Wolf and Dr. rer. Nat. D. Heermann 2006/11/27
Examination to determine the standing time of ID220 with high organic load(blood)

連邦保健局の提案で、消毒液の使用可能期間をDGHMの基準に従い診療条件下に近い2%の血液汚染状況で浸漬試験にて検証された結果、ID220（100%濃度／未希釈）は14日間のテスト期間中、2%の有機物負荷にも関わらず試験細菌の黄色ブドウ球菌、腸内連鎖球菌、緑膿菌及び真菌（カンジダ・アルビカンス）に対し十分な効果を示した。以上の結果より安全性を考慮しても、本品は汚染程度が2%を超えない環境下において最長7日間の使用が推奨されることが証明された。

27.11.2006
WF

DÜRR SYSTEM-HYGIENE
ID 220
Bur Disinfection

Examination to determine the standing time of ID 220 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 220 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 100% undiluted 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 100% ID 220 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

超音波洗浄器使用時のID220の消毒効果の検証

Dr. rer. Nat. K.-M. Wolf and Dr. rer. Nat. D. Heermann 2009/03/09
Investigation into the activity of ID220 when using the ultrasonic cleaner Duerr Hygosonic

DGHMの基準に従い、本品を診療条件下に近い2%の血液汚染状況で超音波洗浄器（デュールハイゴソニック）を使用して浸漬試験にて検証した結果、ID220（100%濃度／未希釈）は試験細菌の黄色ブドウ球菌、腸内連鎖球菌、緑膿菌及び真菌（カンジダ・アルビカンス）に対したった30秒の作用時間で十分な効果を示すことが証明された。

DESINFEKTION · HYGIENE · FOTOCHEMIE

orochemie

09.03.2009
WF

DÜRR SYSTEM-HYGIENE
ID 220
Bur Disinfection

Investigation into the activity of ID 220 when using the ultrasonic cleaner Dürr Hygosonic

The activity of ID 220 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 *forte* could be reduced by using ultrasonic equipment. A 100 % ID 220 solution was effective against the tested bacteria Staphylococcus aureus, Enterococcus hirae, Pseudomonas aeruginosa as well as the yeast Candida albicans within only 30 seconds. 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 220 when used in the ultrasonic cleaner Dürr Hygosonic:

100 % at a **contact time** of **30 seconds**

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

Dr. rer. nat. D. Heermann

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超音波洗浄器使用時のID220の消毒効果の検証

Dr. rer. Nat. K.-M. Wolf and Dr. rer. Nat. D. Heermann 2009/03/09
Investigation into the activity of ID220 when using the ultrasonic cleaner

DGHMの基準に従い、本品を診療条件下に近い2%の血液汚染状況で超音波洗浄器を使用して浸漬試験にて検証した結果、ID220（100%濃度／未希釈）は試験細菌の黄色ブドウ球菌、腸内連鎖球菌、緑膿菌及び真菌（カンジダ・アルビカンス）に対したった30秒の作用時間で十分な効果を示すことが証明された。

01.12.2006
WF

DÜRR SYSTEM-HYGIENE
ID 220
Bur Disinfection

Investigation into the activity of ID 220 when using an ultrasonic cleaner

The activity of ID 220 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 220 could be reduced by using ultrasonic equipment. An undiluted (100%) ID 220 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 30 seconds. 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 220 when used in an ultrasonic cleaner:

100% at a **contact time** of **30 seconds**

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

Dr. rer. nat. D. Heermann

超音波洗浄器使用時のID220の殺結核菌効力の検証

Dr. Holger Brill 2007/05/21

Suitability of ID220 for instrument disinfection (tuberculocidal effect according to EN14563)

EN14563に準じて、医療領域における浸漬試験を行い本液の殺結核菌性効果を検証した結果、ID220（100%濃度／未希釈）は有機物の汚染状況下において、超音波洗浄器の使用で1分、超音波洗浄機未使用で30秒の作用時間で十分な有効性を示すことが証明された。

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Hamburg, 21 May 2007

Expert's report

Suitability of DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion for instrument disinfection (tuberculocidal effect according to DIN EN 14563:2002)

The disinfectant **DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion** 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 methods and requirements (phase 2/step 2)".

According to test report no. L 07/030 from Dr. Brill + Partner GmbH, **DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion** showed a tuberculocidal activity under high organic load.

DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion fulfils the requirements of the norm (RF ≥ 4) by the following concentration-time relation:

100 %	**60 seconds (without ultrasound)**
100 %	**30 seconds (with ultrasound).**

Dr Holger Brill

ID220のワクシニアウイルス不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 2008/05/10
Vaccinia virus efficacy of ID220 in a quantitative suspension test at 20℃

ドイツウイルス疾病管理協会（DVV）及びロベルトコッホ研究所（RKI）のガイドラインに従い、ワクシニアウイルスに対する不活性化効力の定量的浮遊試験を、20℃の環境下でID220（100%濃度／未希釈）を用いて15秒・30秒・60秒の作用時間で評価を行った結果、15秒後に規定のウイルスの減少がみられたことから、ID220（100%濃度／未希釈）は15秒の作用時間でワクシニアウイルス不活性化に有効であることが実証された。

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Vaccinia virus efficacy of DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion in a quantitative suspension test at 20°C according the guideline of DVV/RKI dating 15.06.2005

EXPERT OPINION

This expert opinion is based on the test report O08ML565V dating 10.05.2008.

The virus-inactivating properties of the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion of orochemie against vaccinia virus strain Elstree were investigated by a quantitative suspension test according to the guideline of the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (German Association for the Control of Virus Diseases) and the Robert Koch-Institute (RKI).
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 220 Bohrerdesinfektion was examined undiluted (80.0 %) at 20°C. Exposure times were 15, 30 and 60 seconds. After an exposure time of 15 seconds virus reduction exceeded 4 $\log_{10}$-steps in all assays. Therefore, a virucidal activity was measured as follows:

undiluted 15 s

Dr. J. Steinmann

ID220のC型肝炎ウイルス不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 2001/09/24
BVDV efficacy of ID220

ID220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）及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、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80%濃度／1.25倍希釈の本液を用いて30秒・1分・2分・5分の作用時間で評価を行った結果、ID220(100%濃度/未希釈)は30秒間の作用時間で十分なウイルス不活性化効力を示したことからC型肝炎ウイルス不活性化に有効であることが実証された。

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BVDV efficacy of DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION

EXPERT'S INVESTIGATION REPORT

The virucidal efficacy of the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 220 BOHRERDESINFEKTION 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 220 BOHRERDESINFEKTION was examined as a 80.0% 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 220 BOHRERDESINFEKTION for the inactivation of BVDV as follows:

concentrated **30 seconds**

Dr. J. Steinmann

ID220のアデノウイルス不活性化効力の検証

MikroLab GmbH, Dr. Jochen Steinmann 2006/09/22
Effectiveness of ID220 against adenovirus according to EN14476

EN14476に従い、ID220のアデノウイルス5型に対する不活性化効力の定量的浮遊試験を、100%濃度／未希釈の本液を用いて1分・2分・5分の作用時間で評価を行った結果、ID220(100%濃度/未希釈)は1分間の作用時間で十分なアデノウイルス不活性化効力を示すことが実証された。

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Effectiveness of DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion against adenovirus according to EN 14476:2005

EXPERT OPINION

Effectiveness of the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 220 Bohrer-desinfektion of orochemie was investigated against adenovirus type 5 according to EN 14476:2005. This European standard describes a quantitative suspension test (phase 2, step 1), mixing one part by volume of test virus suspension, one part by volume of interfering substance and eight parts by volume of disinfectant. At specified contact times an aliquot is taken and residual infectivity is determined.

According to EN 14476:2005, a disinfectant is considered as having virucidal effectiveness if within the recommended exposure time the titre is reduced by ≥ four $\log_{10}$-steps (inactivation ≥ 99.99%).

The disinfectant DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion was examined undiluted. The exposure times were 1, 2 and 5 minutes.
After one minute exposure time a reduction factor of ≥ 6.13 was measured under clean and dirty conditions.
Therefore, summarizing the results of the experiments it can be declared that the disinfectant DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion is virucidal against adenovirus type 5 with the following conditions:

undiluted **1 minute**

Dr. J. Steinmann

ID220のポリオーマウイルスSV40への不活性化効力の検証

MikroLab GmbH, Dr.Jochen Steinmann 2008/05/14
SV40 efficacy of ID220 in a quantitative suspension test at 20℃

ドイツウイルス疾病管理協会（DVV）及びロベルトコッホ研究所（RKI）のガイドラインに従い、ポリオーマウイルスSV40に対する不活性化効力の定量的浮遊試験を、100%濃度／未希釈及び10%濃度／10倍希釈の本液を用いて20℃の有機物負荷下及び無負荷の状況下で30秒・60秒・120秒・300秒の作用時間にて評価を行った結果、ID220(100%濃度/未希釈)は30秒間の作用時間で十分なウイルス不活性化効力を示すことが実証された。

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SV40 efficacy of DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion in a quantitative suspension test at 20°C according to the guideline of DVV/RKI dating 15.06.2005

EXPERT OPINION

This expert opinion is based on the test report 08ML565S dating 14.05.2008.

The virus-inactivating properties of the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion of orochemie against Polyomavirus SV40 were investigated by a quantitative suspension test according to the guideline of the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (German Association for the Control of Virus Diseases) and the Robert Koch-Institute (RKI).
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 220 Bohrerdesinfektion was examined undiluted and 10.0 % solution at 20°C. Exposure times were 30, 60, 120, and 300 seconds. In all assays without and with organic load virus reduction exceeded 4 $\log_{10}$-steps after an exposure time of 30 seconds. Therefore, a virucidal activity against SV40 was measured as follows:

undiluted **30 seconds**

Dr. J. Steinmann

ID220のポリオウイルスへの不活性化効力の検証

MikroLab GmbH, Dr.Jochen Steinmann 2006/08/30
Effectiveness of ID220 against poliovirus according to EN14476

EN14476に従い、ポリオウイルス1型に対する不活性化効力の定量的浮遊試験を、100%濃度／未希釈の本液を用いて1分・2分・5分の作用時間にて評価を行った結果、ID220(100%濃度/未希釈)は1分間の作用時間で十分なウイルス不活性化効力を示すことが実証された。

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Effectiveness of DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion against poliovirus according to EN 14476:2005

EXPERT OPINION

Effectiveness of the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 220 Bohrer-desinfektion of orochemie was investigated against poliovirus type 1 according to EN 14476:2005. This European standard describes a quantitative suspension test (phase 2, step 1), mixing one part by volume of test virus suspension, one part by volume of interfering substance and eight parts by volume of disinfectant.
According to EN 14476:2005, a disinfectant is considered as having virucidal effectiveness if within the recommended exposure time the titre is reduced by ≥ four $\log_{10}$-steps (inactivation ≥ 99.99%).
The instrument disinfectant DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion was examined undiluted. The exposure times were 1, 2 and 5 minutes.

After one minute of exposure a reduction factor of ≥ 6.13 (clean conditions) and ≥ 6.38 (dirty conditions) was measured.
Therefore, summarizing the results of the experiments it can be declared that the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 220 Bohrerdesinfektion is virucidal against poliovirus type 1with the following conditions:

undiluted **1 minute**

Dr. J. Steinmann

ID220のエンベロープウイルス及び非エンベローブウイルス不活性化効力の検証

University of Hohenheim, Dr. Dieter Strauch 1985/01/30

Effectiveness of ID220 against enveloped virus and non-enveloped virus

連邦健康管理局（BGA）及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、ID220のエンベロープウイルス及び非エンベロープウイルス不活性化効力を検証するため、有機物負荷下及び無負荷の状況下で定量的浮遊試験を、エンベロープウイルスとしてワクシニアウイルス、非エンベロープウイルスとしてポリオウイルス・アデノウイルス・SV40を選定し100%濃度／未希釈の本液を用いて評価を行った結果、有効成分80%含有のID220（100%濃度/未希釈）はすべてのウイルスに対して5分の作用時間で十分な不活性化効力を示すことが実証された。

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30th January 1985

DÜRR SYSTEM-HYGIENE
Instrument Disinfection ID 220
Ready-diluted solution

EXPERTISE

on the testing of this disinfectant in conformity with the Guidelines of the Federal Health Office (BGA) and the German Association for the Control of Virus Diseases (DVV), as of 01.09.1982, to establish its effectiveness against viruses

According to the manufacturer's specifications, the preparation **DÜRR SYSTEM-HYGIENE Instrument Disinfection ID 220 reday-diluted solution** - hereinafter called **ID 220** - contains a mixture of alcohols in an alcaline solution as disinfecting component.

The given preparation is applied as a concentrate for disinfection purposes. As regards the methodics of the tests conducted to assess the effectiveness as an instrument disinfectant, this means an active concentration substance of 80 vol.-%. However, in compliance with the Commentary on the above Guidelines, as of 12.12.1983, as far as assessing the preparation's effectiveness against viruses is concerned, this deficiency is neglectable.

The preparation **ID 220** was supplied to us by Messrs. OROCHEMIE, Kornwestheim, in a quantity of 1000 ml contained in a brown glass bottle, with the date of manufacture 16.05.1984.

The preparation is a light bluish fluid with a fruit-scented, alcohol-like smell. The pH value of the concentrate is 14.2; an 80 vol.-% concentration has 13.9 pH. This ranks it among the acidic aldehyde disinfectants. It proved to be readily miscible. No protein precipitation could be detected.

Test viruses and indication systems:

- Vaccinia virus, Elstree strain (Poxviridae), as culture virus from vero-cells, i.e. kidney cells of the African Green Monkey (Cercopithecus aethiops). Indication system: vero-cells.
- Polio virus, Mahoney strain (Picornaviridae), as culture virus from vero-cells. Indication system: vero-cells.
- Adeno virus type II, Adenoid 6 strain (Adenoviridae), as culture virus of Hela-cells "Saarbrücken". Indication system: Hela-cells "Saarbrücken".
- SV-40 Virus 777 (Papovaviridae), as culture virus from CV-1 cells of a permanent cell line from the kidneys of African Green Monkeys (Cercopithecus aethiops). Indication system: CV-1 cells.

The virus suspensions were prepared, cleaned and concentrated in compliance with the Guidelines of BGA and DVV as of 01.09.1982, Section 3. The following virus titres were used for the actual test preparations:

- Vaccinia $10^{8.0}$ CID_{50} / ml
- Polio $10^{9.5}$ CID_{50} / ml
- Adeno $10^{9.0}$ CID_{50} / ml
- SV-40 $10^{8.0}$ CID_{50} / ml

Information on the cytotoxicity of the disinfectant:

The preparation was added in 80 vol.-% concentration in PBS (physiological buffered saline solution) as the corresponding conservation medium at diluting ratios between 1 : 10 and 1 : 10000 and transmitted to the cell cultures by inoculation. For the evaluation of the corresponding virus titrations of the test preparations, the cell cultures were then examined for disinfectant-conditioned, unspecific cytotoxic effects. The cytotoxicity of formaldehyde in the prescribed concentration was determined in the same manner.

Indication system	Application Concentration of disinfectant	Dilutions 1 : 10	1 : 100	1 : 1000	1 : 10000
Vero-cells	80 vol.-%	-	-	-	-
Hela-cells	80 vol.-%	tox.	-	-	-
CV-1 cells	80 vol.-%	-	-	-	-
Vero-cells Hela-cells CV-1 cells	Formalin 1.4 vol.-%	tox.	-	-	-

tox. = toxic - = non-toxic

General assessment:

The **ID 220** preparation for the given tests, each of them being conducted in two test series, was added to the test preparations in such a manner that the preparations had an active substance concentration of 80 vol.-%. The preparation was verified for its effect against polio-, adeno- and SV-40 viruses, as representatives of non-enveloped viruses, and against the vaccinia virus as the representative of enveloped viruses. The tests revealed a good virucidal effect of **ID 220** against the listed virus types. All test viruses, with and without albumin, were inactivated within an action period of 5 minutes.

On the basis of the Commentary on the Guidelines of BGA and DVV for testing the effectiveness of chemical disinfectants against viruses in which a minimum reduction of the infectivity titre by 4 powers of ten is demanded to declare an agent as effective, it can be stated in conclusion: The preparation **ID 220** in an 80 vol.-% concentration is effective against viruses after an action period of 5 minutes. It likewise fulfills the preconditions of a suitable disinfectant when used as a concentrate in practice.

ID220のポリオウイルスへの不活性化効力の検証

MikroLab GmbH, Dr.Jochen Steinmann 1991/06/28

Testing the virusidal effectiveness of ID220 on the Polio virus type1

連邦健康管理局（BGA）及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、ポリオウイルス1型に対する不活性化効力の定量的浮遊試験を、80%濃度／1.25倍希釈の本液を用いて評価を行った結果、ID220(100%濃度/未希釈)はポリオウイルスに対し5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。

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June 28, 1991
Dr. St/W

EXPERTISE

on the results of testing the virucidal effectiveness of *ID 220* on the Polio virus, type I, parent Mahoney

DÜRR SYSTEM-HYGIENE
***ID 220* Instrument Disinfection**

The virus-inactivating properties of *ID 220* against the viral species Polio, type I, parent Mahoney, was examined in a suspension test 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.

The instrument disinfectant *ID 220* is a ready-to-use solution for disinfecting and cleaning the rotary dental instrumentaarium containing propanol (15 %) and potassium hydroxide as microbicidal substances. The pH value of the concentrate is 13.9.

Tests on cytotoxicity (tabularly not shown) proved that the 0.7 % formaldehyde solution entrained as test control according to the guidelines was toxically effective on the AM cells applied even in a 0.001 % dilution (log CD_{50} 3.5 analogous to the ID_{50} value). No cytotoxicity was to be found any longer with a further dilution.

ID 220 was tested as 80 % solution only. No cytotoxicity was apparent in the 1 : 10 and 1 : 100 dilution, Consequently, a log CD_{50} value of < 0.5 is the result. These cytotoxicity tests are imperative, in order to determine the limit of detection for non-inactivated polio virus.

Our test results are shown in table 1 and fig. 1. The table reveals that the formaldehyde solution entrained as test control reduced the polio virus titre by 1.4 powers of ten within a 15-minute action period. After 30 or 60 minutes action time, respectively, the log reduction factor was 2.1 and 3.4. The limit of detection was reached after an action time of 2 hours; the log reduction factor was ≥ 3.87.

ID 220 used as an 80 % solution was shown to possess an outstanding virucidal activity against the Polio virus. After only 5 minutes contact time, a reduction in the infectious titre by ≥ 6.87 powers of ten was reached in all three test strains. This corresponds to a percentage inactivation of more than 99.9999. At this time, the limit of detection was reached, so that any further reduction of the infectious titre could no longer be shown.

In order to achieve a reliable virucidal activity of *ID 220* against the polio virus, type I, the following instructions for use are provided:

Recommended application

Instrument Disinfection:

100 % *ID 220* - 5 minutes action period

(Dr. J. Steinmann)

ID220のラットへの急性経口毒性試験

IBR Forschungs GmbH, Dr. W. Sterner 1987/05/22

Testing the acute oral toxicity in rats in conformity with OECD guidelines (limit test)

ID220の急性経口毒性試験をオス5匹及びメス5匹のウィスターラットに対して実施し、14日間の観察期間に現れた臨床的毒性兆候、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、ラットの活動性や反射・立毛反応の減少及び姿勢の変化は見られたが、死亡は確認されず、14日後の体重測定では正常な体重増加を示した。以上の結果より、半数致死量は5078㎎／kgであることが証明され、ID220は低毒性薬液に分類された。

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22nd May 1987 / ti

Project No. 1-4-335-87

DÜRR SYSTEM-HYGIENE
ID 220
Instrument Disinfection

Expertise

on the results of testing the acute oral toxicity in rats in conformity with the OECD guidelines (limit test)

I. TEST OBJECTIVE

The test was carried out in order to establish whether the test substance ID 220 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, or 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 and piloerection.

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

c) There was no case of mortality.
There were no findings at the final dissection (14 days p.a.).

d) Determination of the oral LD_{50} gave the following result:

$$\frac{\text{24 h + 14 days}}{\text{male + female}} \qquad > 5 \text{ ml/kg} \mathrel{\hat{=}} 5078 \text{ mg/kg}$$

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)

ID220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 1997/08/11

Test report concerning the biodegradability of the ID220 in the closed bottle test

ID220の生分解性を検証するため密閉ボトル試験を実施した結果、酸素消費量に基づいたID220の生分解性は化学的酸素要求量（COD）と比較され28日後に72%と測定された。以上の結果より、ID220は易生分解性溶液に分類された。

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August 11, 1997

No. 05174057

TEST REPORT CONCERNING THE BIODEGRADABILITY OF THE DÜRR SYSTEM-HYGIENE ID 220 BUR DISINFECTION IN THE CLOSED BOTTLE TEST

Evaluation:

The total decomposition of the test substance after 28 days is 72 % biological oxygen demand (BOD) of the chemical oxygen demand (COD). The test substance „DÜRR SYSTEM-HYGIENE ID 220 Bur Disinfection“ has to be classified as „**easily biodegradable**“.

Bad Bocklet, August 11, 1997

Prof. Dr. B. Sonnenschein　　i.V. U. Hamann

GA/engl/19.02.98
ls-lab2/st

ID220の原料適合性試験

Orochemie, Dr. rer. nat. D. Heermann 1997/04/16
Expertise on the results of testing the material compatibility of ID220

ID220の原料適合性を検証するため、バー・根幹治療器具・ブローチ・ファイルなどの異なる材質の歯科回転器具に対して以下の試験を実施した。2つの新しいバーを一晩ID220に浸漬し（1週間に1回新しい液に取り換え）、翌朝水洗後1日布の上で乾燥させる工程を、9週間に渡って実施した結果、材料及び色に変化は無く、回転器具の機能性の低下もみられなかった。

OROCHEMIE
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April 16, 1997
HE/DE/TE

DÜRR SYSTEM-HYGIENE
ID 220
Bur Disinfection

Expertise
on the results of testing the material compatibility of ID 220

The aim of the test was to determine the material compatibility of ID 220 with rotary dental instrumentarium.

Different rotary instruments as for ex. rose burs, root canal instruments, nerve broaches, files, etc. were tested for resisting against ID 220.

There were put 2 new burs into a cup for a whole night, in the morning it was rinced with water, taken out and during one day put onto a fleece for drying.

The testing period lasted 9 weeks.

The solutions were renewed once per week.

Results
The immersion with ID 220 resulted in **no** material changes over the burs, especially the colours were neither affected nor did they peel off. It could not be detected a reduction of the function upon the tested rotary instruments.

(Dr. rer. nat. D.Heermann)

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

ID220の歯科回転器具への材料適合性試験

Orochemie, Dr. rer. nat. Klaus-Michael Wolf and Dipl. Ing. Peter Brauner 2006/01/13
Test for residues on rotary instruments when using ID220

ID220のプローベ・ミラー・ピンセット・梃子・練和スパチュラなどの歯科器具への材料適合性と水洗の推奨を検証するため以下の試験を実施した。100mlの本液をザル付きの容器に入れ、1分間40ｇ分の回転器具を浸漬した後、液から上げて30秒間ザルで液を切り、100mlの水が入った別の容器に浸漬後再度30秒間ザルで水を切りその後さらに3度水洗工程を繰り返した結果、100mlのID220に40gの器具を浸漬した後に完全に本液を洗い流すには200mlの水での水洗が有効であることが証明された。以上の結果より、ID220使後は器具のステイン防止のため200ml～400mlの水で10～15秒間水洗し乾燥させることが推奨される。

DESINFEKTION · HYGIENE · FOTOCHEMIE

orochemie

13 January 2006
WF/DW

DÜRR SYSTEM-HYGIENE ID 220 Bur Disinfection
Test for Residues on Rotary Instruments when Using ID 220 Solutions

It was the objective of the test to determine residues of ID 220 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 220 is an aqueous, alcohol-based ready-to-use disinfectant solution. Due to the good water solubility of the ingredients of ID 220, the tests were based on the assumption that residues of the ingredients of ID 220 cannot be found on disinfected instruments when the ingredients cannot be detected in the rinsing liquid.

Experimental Procedure:

100 ml of ID 220 ready-to-use solution (Ch.-B. 25097) were poured into a container (fraise) with tray and charged with rotary instruments, e.g. drills, root canal instruments, polishers, etc. (40 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 100 ml water. The tray with the rotary 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 active ingredient propan-1-ol 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 40 g of instruments with in all 0.2 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 ID 220 were removed from the solution and thus from the instruments by rinsing them with in all 0.2 litres of water.

The following recommendation for use can be given for the practice: Rinse instruments with 0.2 to 0.4 litres of water for approx. 10 to 15 seconds. To avoid stains when sterilizing the instruments, rinse them with demineralised water and dry or leave to dry.

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