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

ID213 instrument disinfection
インスツルメント｜器具の除菌



2019年2月現在

DÜRR DENTAL

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インスツルメント｜器具の除菌

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ID213の菌及び真菌（C.アルビカンス）による汚染状況下での効能性

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

ID213 Instrument Desinfection, Bacterial and fungicidal (C. albicans) efficiancy, Dirty conditions

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、ID213（1.0%濃度）は5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 213 Instrument disinfection
Instrument disinfection
Bactericidal and fungicidal (C. albicans) efficacy
Dirty conditions

EXPERTISE

After testing the disinfectant **DÜRR SYSTEM-HYGIENE ID 213 Instrument disinfection** in accordance with the

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

I hereby issue the following evaluation of the results from the test report 2005-02-15 (SN 4137):

Results of the in vitro-tests

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

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

DÜRR SYSTEM-HYGIENE ID 213 Instrument disinfection resulted in sufficient reductions (5 lg. cfu of the test strains S. aureus, E. hirae und P. aeruginosa and 4 lg. cfu of C. albicans) under **dirty conditions**

in 1.0 %	within	5 minutes as well as
in 0.5 %	within	15 minutes.

Results of tests simulating conditions in practice

The efficacy of the disinfectant **DÜRR SYSTEM-HYGIENE ID 213 Instrument disinfection** was also analysed in these test runs **under dirty conditions**.

Under this conditions demonstrated

1.0 % within 5 minutes

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

Application recommendations for
DÜRR SYSTEM-HYGIENE ID 213 Instrument disinfection
for disinfection of instruments

According to the results obtained, **DÜRR SYSTEM-HYGIENE ID 213 Instrument disinfection** complies with the

„Requirements Specification for the Certification of Chemical Disinfection Processes by the disinfectant commission of VAH"

under **dirty conditions** against S. aureus, E. hirae, P. aeruginosa and C. albicans

in 1.0 % within 5 minutes.

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

ID213の殺菌と殺ウイルス活性、及び結核菌への効力の検証

Dipl. Biol. Dr. Rer. Nat. Florian H. H. Brill 2013/08/08
ID213 Instrumentendesinfektion under dirty conditions (DGHM catalog of requirements 2002, chapter 11.1 and 11.2)

DGHMのガイドラインに従い、汚染状況下における殺菌性、殺ウイルス活性及び結核菌への効力の検証を行った結果、ID213は以下の条件下で十分な有効性を示し、VAHリストに下記のように記載された。
殺菌　2.0% 5分、0.5% 30分
殺ウイルス　2.0% 15分、0.5% 60分
結核菌　2.0% 30分、1.0% 60分

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Hamburg, 8 August 2013

Expert Report

Instrument Disinfection with **DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion** under dirty conditions (DGHM Cataloge of Requirements 2002, Chapter 11.1 and 11.2)

The instrument disinfectant **DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion** was tested according to the "DGHM standard methods for testing chemical disinfection procedures" (as of 1 September 2001) and evaluated according to the "List of requirements for inclusion of chemical disinfection procedures in the DGHM list of disinfectants" (as of 4 February 2002).

According to expert report dated 21 December 2004 and the test report no L12/308 dated 7 May 2013 as well as test report no L12/308.2 dated 8 August 2013 from Dr. Brill + Partner GmbH, the test preparation showed sufficient activity for instrument disinfection under dirty conditions.

The recommendation for listing **DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion** in the column for dirty conditions into the VAH-list is:

Bactericidal and levurocidal activity:		**Tuberculocidal activity:**	
2.0 %	**5 minutes**	**2.0 %**	**30 minutes**
2.0 %	**15 minutes**	**1.0 %**	**60 minutes**
0.5 %	**30 minutes**		
0.5 %	**60 minutes**		

Dr. Florian H. H. Brill

DGHMガイドラインに準じたアスペルギウスに対するID213の効力の検証

Dr. Rer. Nat. Holger Brill 2005/03/18

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

DGHMのガイドラインに従い、アスペルギウス・ニガーを用いて殺真菌性効力の検証を行った結果、ID213は30分間（2.0%濃度）、または60分間（1.0%濃度）での作用時間でマイコバクテリウム及びアスペルギウス・ニガーに対し十分な有効性を示した。

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Hamburg, 18 March 2005

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

The instrument disinfectant ***DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion*** was tested additionally in its efficacy against Aspergillus niger 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 fungicidal, as it is effective against the test germ *Aspergillus niger*.

The use-recommendation for ***DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion*** for chemical instrument disinfection against *Aspergillus niger* is:

1.0 % 5 minutes
0.5 % 15 minutes
0.25 % 30 minutes
0.125 % 60 minutes

The use-recommendation for ***DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion*** for chemical instrument disinfection including the data of the expert report dated 9 November 2004 and the now available expert report dated 18 March 2005, which includes the efficacy test against *Mycobacterium terrae* and *Aspergillus niger*, is:

2.0 % 30 minutes
1.0 % 60 minutes.

Dr. Holger Brill

ID213の菌及び真菌（C.アルビカンス）による汚染状況下での効能性

Prof. Dr. Med. H.-P. Werner 2012/08/20

ID213 Instrument disinfection, bacterial and yeasticidal (C. albicans) effictiveness, Dirty conditions

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、ID213（1.0%濃度）は5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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DEUTSCHLAND

2012-08-20

Prof.We

DÜRR SYSTEM-HYGIENE ID 213
Instrument disinfection
Bactericidal and yeasticidal (C. albicans) effectiveness
Dirty conditions

EXPERTISE

Having tested the disinfectant **DÜRR SYSTEM-HYGIENE ID 213** in accordance with the "Standard methods of the DGHM*) for testing of chemical disinfection methods" (Status: 2001-09-01)

I hereby issue the following evaluation of the results from the test report of 2012-08-20 B 17622a (test product: WF-312):

Results of the in vitro-test

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

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

*) DGHM = German society for Hygiene and Microbiology.

DÜRR SYSTEM-HYGIENE ID 213 results in sufficient reductions (5 lg units of test bacteria S. aureus, E. hirae and P. aeruginosa or 4 lg units of C. albicans)

under dirty conditions

in 1.0 %	within	5 minutes and
in 0.25 %	within	15 minutes.

Results obtained in tests simulating conditions in practice

The efficacy of the disinfectant **DÜRR SYSTEM-HYGIENE ID 213** was tested under **dirty conditions**.

Under **dirty conditions** in

1.0 %	within	5 minutes

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

Application recommendation for DÜRR SYSTEM-HYGIENE ID 213 for instrument disinfection

According to the results obtained, **DÜRR SYSTEM-HYGIENE ID 213** complies with the

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

under **dirty conditions** in

1.0 %	in	5 minutes.

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

*) VAH= Verbund für angewandte Hygiene

ID213の結核菌(マイコバクテリウム)による汚染状況下での殺菌効能性の検証

Prof. Dr. Med. H.-P. Werner 2012/08/27

ID213 Instrument disinfection, tuberculocidal (M. terrae) effictiveness, Dirty conditions

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マイコバクテリウムに対して行った結果、ID213（2.0%濃度）は60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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DEUTSCHLAND

2012-08-27

Prof.We

DÜRR SYSTEM-HYGIENE ID 213
Instrument disinfection
Tuberculocidal (*M. terrae*) effectiveness
Dirty conditions

EXPERTISE

Having tested the disinfectant **DÜRR SYSTEM-HYGIENE ID 213** in accordance with the

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

I hereby issue the following evaluation of the results for tuberculocidal effectiveness from the test report of 2012-08-27 B 17622b (test product: WF-312):

Results of the in vitro-test

The quantitative suspension tests were carried out in spread plate technique for germ detections under **dirty conditions**, test germs *Mycobacterium terrae*.

DÜRR SYSTEM-HYGIENE ID 213 results in sufficient reductions (4 lg units)
under dirty conditions

in 1.0 % within 60 minutes.

*) DGHM = German society for Hygiene and Microbiology.

Results obtained in tests simulating conditions in practice

The efficacy of the disinfectant **DÜRR SYSTEM-HYGIENE ID 213** was tested under **dirty conditions**.

Under **dirty conditions** in

2.0 % within 60 minutes

showed sufficient efficacy against the test germ *M. terrae*.

Application recommendation for DÜRR SYSTEM-HYGIENE ID 213 for tuberculocidal instrument disinfection

According to the results obtained, **DÜRR SYSTEM-HYGIENE ID 213** complies with the

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

under **dirty conditions** in

2.0 % within 60 minutes.

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

*) VAH= Verbund für angewandte Hygiene

ID213の結核菌による汚染状況下での殺菌効能性の検証

Prof. Dr. Med. H.-P. Werner 2005/03/17
ID213 Instrument disinfection, tuberculocidal efficiency, Dirty conditions

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マイコバクテリウムに対して行った結果、ID213（2.0%濃度）は60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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2005-03-17

DÜRR SYSTEM-HYGIENE ID 213 Instrument disinfection
Instrument disinfection
Tuberculocidal efficacy
Dirty conditions

EXPERTISE

After testing the disinfectant **DÜRR SYSTEM-HYGIENE ID 213 Instrument disinfection** in accordance with the

„Standard Methods of the DGHM for testing of chemical disinfection processes"
(Status: 2001-09-01)
included prEN 14563 (Status: Nov. 2002)

I hereby issue the following evaluation of the results from the test report 2005-03-15 (SN 4137):

Results of the in vitro-tests

The quantitative suspension tests were carried out under **dirty conditions**.

DÜRR SYSTEM-HYGIENE ID 213 Instrument disinfection resulted in sufficient reductions (4 lg. cfu of the test strain M. terrae) under **dirty conditions**

in 2.0 % within 60 minutes.

Results simulating conditions in practice

The efficacy of the disinfectant **DÜRR SYSTEM-HYGIENE ID 213 Instrument disinfection** was also analysed in these test runs **under dirty conditions**.

Under this conditions the test product demonstrated

2.0 % within 60 minutes

a sufficient efficacy against the test strain M. terrae.

Application recommendations for
DÜRR SYSTEM-HYGIENE ID 213 Instrument disinfection
for disinfection of instruments -
tuberculocidal efficacy

According to the results obtained, **DÜRR SYSTEM-HYGIENE ID 213 Instrument disinfection** complies with the

„Requirements Specification for the Certification of Chemical Disinfection Processes by the disinfectant commission of VAH"

Tuberculocidal efficacy under **dirty conditions**

with 2.0 % within 60 minutes.

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

ID213の定量的浮遊試験における殺菌性

Hygcen, Centrum für Hygiene und medizinische Produktsicherheit 2005/03/08
ID213 Instrument disinfection, DIN EN 13727 (March 2004), Quantitative suspension test, bactericidal activity

IID213の殺菌力評価のために、医療領域における定量的浮遊試験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌に対して標準硬度の20±1℃の水を使用し、2.0%・1.0%・0.5%・0.25%の4種の濃度にて1分・5分・60分の作用時間で評価を行った結果、黄色ブドウ球菌、腸内連鎖球菌、緑膿菌汚染状況下（0.3%ヒツジ赤血球+0.3%牛アルブミン）においてID213（1.0%濃度）は1分間の作用時間で十分な有効性を示した。

PROF. DR. MED. H.-P. WERNER
FACHARZT FÜR HYGIENE UND MIKROBIOLOGIE

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DEUTSCHLAND

2012-08-27
Prof.We

DÜRR SYSTEM-HYGIENE ID 213
Instrument disinfection
Tuberculocidal (*M. terrae*) effectiveness
Dirty conditions

EXPERTISE

Having tested the disinfectant **DÜRR SYSTEM-HYGIENE ID 213** in accordance with the
"Standard methods of the DGHM*) for testing of chemical disinfection methods"
(Status: 2001-09-01)

I hereby issue the following evaluation of the results for tuberculocidal effectiveness from the test report of 2012-08-27 B 17622b (test product: WF-312):

Results of the in vitro-test

The quantitative suspension tests were carried out in spread plate technique for germ detections under **dirty conditions**, test germs *Mycobacterium terrae*.

DÜRR SYSTEM-HYGIENE ID 213 results in sufficient reductions (4 lg units)
under dirty conditions

in 1.0 % within 60 minutes.

*) DGHM = German society for Hygiene and Microbiology.

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Test method:	**DIN EN 13727 (March 2004)** **Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area** **(phase 2, step 1)**
Neutralisation:	S. aureus ; E. hirae: membrane filtration P. aeruginosa: dilution-neutralisation
Period of analysis:	2005-01-31 to 2005-02-20
Diluent:	Water of standardized hardness
Test temperature:	20 ± 1 °C
Product test concentrations:	2.0 %, 1.0 %, 0.5 %, 0.25 % (v/v end concentrations)
Contact times:	1.0 min., 5.0 min., 60 min.
stability and appearance of the mixture during the procedure:	no precipitate or flocculent
Counting procedure:	S. aureus ; E. hirae: spread plate method P. aeruginosa: pour plate method
Incubation:	48 h at 36 °C ± 1 °C
Neutralizer:	3.0 % polysorbate 80 + 3.0 % saponine + 0.1 % histidine + 0.1 % cysteine
Interfering substance:	0.3 % albumine + 0.3 % sheep-erythrocytes (dirty conditions)
Test strains:	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442

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Conclusion:	According DIN EN 13727 (March 2004) the batch 25138 of the product DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion possesses a bactericidal activity for the test strains *Staphylococcus aureus*, *Enterococcus hirae* and *Pseudomonas aeruginosa* under dirty conditions (0.3 % albumine + 0.3 % sheep-erythrocytes) in 1 minute when diluted at 1.0 % (v/v) in water of standardized hardness.
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

K. Naujox
Department manager

ID213の希釈中和法を用いた定量的浮遊試験における殺菌性

Dr. Rer. Nat. Holger Brill 2005/03/18

Determination of bacterial effect of ID213 Instrument disinfection accord. EN 13727:2003

ID213の希釈中和法を用いた殺菌力評価のために、定量的浮遊試験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌に対して標準硬度の20±1℃の水を用いて本液を、0.01%・0.1%・0.25%・0.5%・1.0%の5種の濃度にて希釈し15分・60分の作用時間で評価を行った結果、ID213は黄色ブドウ球菌、腸内連鎖球菌、緑膿菌汚染状況下（0.3%ヒツジ赤血球+0.3%牛アルブミン）において15分間（1.0%濃度）または、60分間（0.25%）の作用時間で十分な有効性を示した。

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Determination of bactericidal effect of

DÜRR SYSTEM-HYGIENE ID 213 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 the sample

• Name of product:	DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion
• Batch number:	23051
• Manufacturer:	orochemie Dürr + Pflug GmbH & Co. KG, Kornwestheim
• Date of supply:	21.05.2004
• Storage conditions:	room temperature and darkness
• Appearance of product and its dilutions:	clear, bluegreen solution
• Odour:	aromatic, fresh
• pH value, concentrate:	11.1
• pH value, 1 %:	9.0
• Recommended diluent:	potable drinking water
• Active agents and concentration:	15.0 g 3-aminopropyl-dodecyl-1,3-propandiamine 12.5 g alkyl-benzyl-dimethyl-ammonium chloride

c) Test procedure and its validation

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

d) Test conditions

– Period of testing:	14.02.2005 to 18.03.2005	
– Product diluent:	sterile water of standardised hardness, 300 mg/kg $CaCO_3$	
– Product test concentrations:	0.01; 0.1; 0.25; 0.5; 1.0 % volume concentration	
– Exposure times:	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 the 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 23051 of the product ***„DÜRR SYSTEM-HYGIENE ID 213 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:

1.0 % 15 minutes
0.25 % 60 minutes.

g) Hamburg, 18.03.2005, Dr. Holger Brill

ID213の希釈中和法を用いた定量的浮遊試験における殺真菌性

Hygcen, Centrum für Hygiene und medizinische Produktsicherheit 2005/03/08

ID213 Instrument disinfection, DIN EN 13624 (Feb 2004), Quantitative suspension test, evaluation of fungicidal activity

ID213の希釈中和法を用いた殺真菌力評価のために、医療領域における定量的浮遊試験をカンジダ・アルビカンスに対して標準硬度の30±1℃の水を用いて本液を、2.0%・1.0%・0.5%の3種の濃度にて希釈し1分・5分・60分の作用時間で評価を行った結果、20℃の真菌（カンジダ・アルビカンス）汚染状況下（0.3%ヒツジ赤血球+0.3%牛アルブミン）においてID213（0.5%濃度）は1分間の作用時間で十分な有効性を示した。

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2005-01-28
Prof. We/ku

DÜRR SYSTEM-HYGIENE ID 213 INSTRUMENTENDESINFEKTION
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 213 INSTRUMENTENDESINFEKTION
Identification of the test laboratory:	SN 4137
Date of delivery:	2004-07-09
Batch number :	25138
Manufacturer:	orochemie
Storage conditions:	those of the manufacturer
Active substances per 100 g:	15.0 g 3-Aminopropyl-dodecyl-1,3-propandiamine, 12.5 g Alkyl-benzyl-dimethyl- ammoniumchloride
Appearance:	clear green liquid
Odour:	aromatic

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Method:	**DIN EN 13624 (February 2004) Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area (phase 2, step 1)**
Neutralisation method:	dilution neutralisation method
Period of analysis:	2005-01-26 to 2005-01-28
Test temperature:	20 ± 1 °C
Product test concentrations:	2.0 %, 1.0 %, 0.5 % (v/v endconcentrationes)
Contact times:	1 min., 5 min., 60 min.
Counting procedure:	pour plate method
Temperature of incubation:	30 °C ± 1 °C
Diluent:	water of standardised hardness
Stability of the mixture, (interfering substance and product diluted in hard water):	no precipitate or flocculent
Neutralizer:	3.0 % polysorbate 80 + 3.0 % saponine + 0.1 % histidine + 0.1 % cysteine
Interfering substance:	dirty conditions: 3.0 g/l albumine + 3.0 ml/l sheep-erythrocytes
Test strain:	*Candida albicans* ATCC 10231

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Conclusion: According to DIN EN 13624 (February 2004) the batch 25138 of product DÜRR SYSTEM-HYGIENE ID 213 INSTRUMENTENDESINFEKTION possesses a fungicidal activity at 20 °C under dirty conditions in 1 min. for the referenced strain *Candida albicans* when diluted at 0,5 % (v/v) in water of standardised hardness.

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

Kathrin Naujox
Department manager

ID213の希釈中和法を用いた定量的浮遊試験における殺真菌性

Dr. Rer. Nat. Holger Brill 2005/03/17

ID213 Instrument disinfection, according to EN13624: 2003

ID213の希釈中和法を用いた殺真菌力評価のために、医療領域における定量的浮遊試験をカンジダ・アルビカンス及びアスペルギウス・ニガーに対して標準硬度の30±1℃の水を用いて本液を、0.125%・0.25%・0.5%・1.0%の4種の濃度にて希釈し5分・15分・30分・60分の作用時間で評価を行った結果、ID213は20℃の真菌（カンジダ・アルビカンス及びアスペルギウス・ニガー）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、それぞれ以下の濃度と作用時間で十分な有効性を示した。カンジダ・アルビカンス　0.5% 15分、0.25% 30分、0.125% 60分 アスペルギウス・ニガー　0.5% 30分、0.5% 60分

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Determination of the fungicidal effect of

DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion according to EN 13624: 2003

a) Identification of the test laboratory:

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

b) Identification of the sample:

• Name of the product:	DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion
• Batch number:	23051
• Manufacturer:	orochemie Dürr + Pflug GmbH & Co. KG, Kornwestheim
• Date of supply:	21.05.2004
• Storage conditions:	room temperature and darkness
• Appearence of the product and its dilutions:	clear, blue-green solution
• Odour:	aromatic, fresh
• pH-value, concentrate:	11.1
• pH-value, 1 %:	9.0
• Recommended diluent:	potable drinking water
• Active agents and concentration:	15.0 g 3-aminopropyl-dodecyl-1.3-propandiamine 12.5 g alkyl-benzyl-dimethyl-ammonium chloride

c) Test procedure and its validation:

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

d) Test conditions:

– Period of the testing:	23.03.2005 to 08.04.2005	
– Product diluent:	sterile water of standardised hardness, 300 mg/kg $CaCO_3$	
– Product test concentrations:	0.125; 0.25; 0.5; 1.0 % volume concentration	
– Exposure times:	5, 15, 30, 60 minutes	
– Test temperature:	20°C ± 1°C	
– Organic load, high:	3 g/L sheep erythrocytes + 3 g/L bovine serum albumine	
– Incubation temperature:	30°C ± 1°C	
– Identification of the fungi strains used:	Candida albicans	ATCC 10231
	Aspergillus niger	ATCC 16404

e) Test results:

The test results are summarised in the table 1 and 2.

f) Conclusions:

In accordance with prEN 13624 (2003), the batch 23051 of ***„DÜRR SYSTEM-HYGIENE ID 213 Instrumententdesinfektion"*** shows in a dilution with water of standardised hardness under high organic load (3 g/L sheep erythrocytes + 3 g/l bovine albumin) a fungicidal effect with regard to the germs tested Candida albicans and Aspergillus niger.

Folgende Konzentrations-Zeit-Relationen erwiesen sich als ausreichend wirksam gegen Candida albicans:

0.5 %	**15 minutes**
0.25 %	**30 minutes**
0.125 %	**60 minutes**

The following concentration-time relationships proved to be sufficiently effective against Aspergillus niger:

0.5 %	**30 minutes**
0.5 %	**60 minutes**

g) Hamburg, 18.04.2005, Dr. Holger Brill

ID213の希釈中和法を用いた定量的浮遊試験における殺結核菌（マイコバクテリウム）性

Prof.We/ku HygCen GmbH 2005/01/15
ID213 Instrument disinfection mycobactericidal activity-prEN 14348

ID213の希釈中和法を用いた殺結核菌力評価のために、医療領域における定量的浮遊試験をマイコバクテリウムに対して標準硬度の36±1℃の水を用いて本液を、4.0%・2.0%・1.0%の3種の濃度にて希釈し15分・30分・60分の作用時間で評価を行った結果、ID213は結核菌（マイコバクテリウム）汚染状況下において30分間（2.0%濃度／硬水希釈）または、60分間（1.0%／硬水希釈）の作用時間で十分な有効性を示した。

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2005-01-05
Prof. We/ku

DÜRR SYSTEM-HYGIENE ID 213
Instrumentendesinfektion
mycobactericidal activity – prEN 14348
(phase2, step1)

TESTREPORT

Identification of the test laboratory:	SN 4137
Test product:	WF-312
Batch number:	Ch.-B.: 25138
Manufacturer:	orochemie
Date of order:	2004-10-04
Date of delivery:	2004-10-08
Storage conditions:	those of the manufacturer
Product diluent recommended by the manufacturer for use:	tap water
Appearance:	clear, green liquid
Odour:	aromatic
Active substances:	per 100 g: 15 g 3-Aminopropyl-dodecyl-1,3-propandiamin, 12.5 g Alkyl-benzyl-dimethyl-ammoniumchlorid

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test method:	prEN 14348 (2002) Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants (phase 2, step1)
inactivation method:	dilution-neutralisation
period of analysis:	2004-11-19 to 2004-12-04
diluent used for product test solution:	water of standardized hardness
test temperature:	20 °C ± 1 °C
Product test concentrations:	4.0%, 2.0%, 1.0% (endconcentrations v/v)
contact times:	15 min., 30min., 60min
stability and appearance of the mixture during the procedure:	no precipitate or flocculent
counting procedure:	surface spread plate
incubation:	36 °C ± 1 °C – 21 d
neutralizer or rinsing liquid:	1.0 % polysorbate 80 + 3.0 % saponine + 0.1 % histidine + 0.5 % sodium thiosulphate
test organism:	*Mycobacterium terrae* ATCC 15755
pH-value (DIN 19266):	4 %: 9.98 2 %: 9.75 1 %: 9.38

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Conclusion: According to prEN 14348 (09/2002), the product WF-312, DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion, possesses a tuberculocidal activity under dirty conditions for the referenced strain *Mycobacterium terrae* in 30 minutes when diluted at 2.0% (v/v) in hard water and in 60 minutes when diluted at 1.0% (v/v) in hard water.

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

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Manager of technical affairs

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ID213の希釈中和法を用いた定量的浮遊試験における殺結核菌（マイコバクテリウム）性

Dr.Rer Nat Holger Brill 2004/05/24

Determination of the tuberculocidal effect of ID213 Instrument disinfection according to EN 14348:2004

ID213の希釈中和法を用いた殺結核菌力評価のために、定量的浮遊試験をマイコバクテリウムに対して標準硬度の36±1℃の水を用いて本液を、0.5%・1.0%・2.0%・3.0%の4種の濃度にて希釈し15分・30分・60分の作用時間で評価を行った結果、ID213は結核菌（マイコバクテリウム）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15分間（2.0%濃度）、30分間（1.0%濃度）または60分間（0.5%濃度）の作用時間で十分な有効性を示した。

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Determination of the tuberculocidal effect of

DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion according to EN 14348: 2004

a) Identification of the test laboratory:

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

b) Identification of the sample:

• Name of the product:	DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion
• Batch number:	23051
• Manufacturer:	orochemie Dürr + Pflug GmbH & Co. KG, Kornwestheim
• Date of supply:	24.05.2004
• Storage conditions:	room temperature and darkness
• Appearance of product and its dilutions:	clear, blue green solution
• Odour:	aromatic, fresh
• Recommended diluent:	potable drinking water
• Active agents and concentration:	15.0 g 3-aminopropyl-dodecyl-1.3-propandiamine 12.5 g alkyl-benzyl-dimethyl-ammonium chloride

c) Test procedure and its validation:

• Test procedure:	Quantitative suspension test (phase 2/step 1)
• Method:	Dilution-neutralisation method
• Neutraliser:	30 g/L polysorbate 80; 30 g/L saponine; 1 g/L histidine; 5 g/L sodium thiosulphate in phosphate buffer (TSH-NT)

d) Test conditions:

– Period of testing:	15.03.2005 to 12.04.2005
– Product diluent:	sterile water of standardised hardness, 300 mg/kg $CaCO_3$
– Product test concentrations:	0.5; 1.0; 2.0; 3.0 % volume concentration
– Exposure times:	15, 30, 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 the microbial strains used:	Mycobacterium terrae ATCC 15755

e) Test results:

The test results are summarised in table 1.

f) Conclusions:

In accordance with EN 14348 (2004), the batch 23051 of the product ***„DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion"*** shows in a dilution with hard water under high organic load (3 g/L sheep erythrocytes + 3 g/l bovine albumine) a tuberculocidal effect with regard to the germ tested Mycobacterium terrae. The following concentration-time relationships proved to be sufficiently effective:

2.0 % 15 minutes
1.0 % 30 minutes
0.5 % 60 minutes

g) Hamburg, 18.04.2005, Dr. Holger Brill

ID213の希釈中和法を用いた定量的浮遊試験における殺菌性

Prof.We/ku HygCen GmbH 2005/01/05

ID213 Instrument disinfection bactericidal activity of chemical disinfectants for instruments-prEN 14561

ID213の殺菌力評価のために、医療領域における定量的浮遊試験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌に対して標準硬度の36±1℃の水を使用し、4.0%・2.0%・1.0%の3種の濃度にて1分・5分・15分・30分・60分の作用時間で評価を行った結果、黄色ブドウ球菌、腸内連鎖球菌、緑膿菌汚染状況下（0.3%ヒツジ赤血球＋0.3%牛アルブミン）においてID213（1.0%濃度／硬水希釈）は5分間の作用時間で十分な有効性を示した。

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ZLG-P-715.98.13

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Max-Planck-Str. 27

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2005-01-05
Prof. We/ku

DÜRR SYSTEM-HYGIENE ID 213
Instrumentendesinfektion
Quantitative carrier test - bactericidal activity of chemical disinfectants for instruments – prEN 14561
(phase2, step2)

TESTREPORT

Identification of the test laboratory:	SN 4137
Test product:	WF-312
Batch number:	Ch.-B.: 25138
Manufacturer:	Orochemie
Date of delivery:	2004-10-08
Date of order:	2004-10-04
Storage conditions:	those of the manufacturer
Product diluent recommended by the manufacturer for use:	tap water
Appearance:	clear, green liquid
Odour:	aromatic
Active substances:	per 100 g: 15 g 3-Aminopropyl-dodecyl-1,3-propandiamin, 12.5 g Alkyl-benzyl-dimethyl-ammoniumchlorid

SN 4137 prEN 14561 page 1 of 9

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test method:	prEN 14561 (Nov 2002) Quantitative carrier test for evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area (phase 2, step2)
inactivation method:	dilution-neutralisation
period of analysis:	2004-12-03 to 2004-12-05
diluent used for product test solution:	water of standardized hardness
test temperature:	20 °C ± 1 °C
Product test concentrations:	4.0%, 2.0%, 1.0% (endconcentrations v/v)
contact times:	1min., 5min., 15 min., 30 min., 60min.
interfering substances:	3,0g/l bovine albumin + 3,0ml/l sheep erythrozytes (dirty conditions)
stability and appearance of the mixture during the procedure:	no precipitate or flocculent
counting procedure:	surface spread plate
incubation:	36 °C ± 1 °C – 48h
neutralizer or rinsing liquid:	3.0 % polysorbate 80 + 3.0 % saponine + 0.1 % histidine + 0.1 % cysteine
test organisms:	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442

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Conclusion: According to prEN 14561 (11/2002), the batch Ch.-B.: 25138 of product WF-312, DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion, possesses a bactericidal activity under dirty conditions for the referenced strains *Staphylococcus aureus*, *Enterococcus hirae* and *Pseudomonas aeruginosa* within 5 minutes when diluted at 1.0% (v/v) in hard water.

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

HygCen
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med. Produktsicherheit GmbH

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

K. Naujox
Department manager

ID213の希釈中和法を用いた定量的浮遊試験における殺菌性

Dr.Rer Nat Holger Brill 2005/01/05

ID213 Instrument disinfection according to EN 14561:2002

ID213の殺菌力評価のために、定量的浮遊試験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌に対して標準硬度の36±1℃の水を使用し、0.1%・0.5%・1.0%・2.0%・3.0%の5種の濃度にて15分・30分・60分の作用時間で評価を行った結果、ID213は黄色ブドウ球菌、腸内連鎖球菌、緑膿菌汚染状況下（0.3%ヒツジ赤血球+0.3%牛アルブミン）において15分間（2.0%濃度）、30分間（1.0%濃度）または60分間（0.5%濃度）の作用時間で十分な有効性を示した。

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Determination of bactericidal effect of

DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion according to EN 14561: 2002

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 the sample

• Name of product:	DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion
• Batch number:	23051
• Manufacturer:	orochemie Dürr + Pflug GmbH & Co. KG, Kornwestheim
• Date of supply:	24.05.2004
• Storage conditions:	room temperature and darkness
• Appearance of product and its dilutions:	clear, blue green solution
• Odour:	aromatic, fresh
• Recommended diluent:	potable drinking water
• Active agents and concentration:	15.0 g 3-aminopropyl-dodecyl-1,3-propandiamine 12.5 g alkyl-benzyl-dimethyl-ammonium chloride

c) Test procedure and its validation

• Test procedure:	Quantitative carrier test with glass-germ carriers (phase 2/step 2)
• Method:	Dilution-neutralisation method
• Neutraliser:	30 g/L polysorbate 80; 30 g/L saponin; 1 g/L histidine; 5 g/L sodium thiosulphate in phosphate buffer (TSH-NT)

d) Test conditions

– Period of the testing:	12.01.2005 to 19.01.2005	
– Product diluent:	sterile water of standardised hardness, 300 mg/kg $CaCO_3$	
– Product test concentrations:	0.1; 0.5; 1.0; 2.0; 3.0 % volume concentration	
– Exposure times:	15, 30, 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 the 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 1.1 and 1.2.

f) Conclusions

In accordance with prEN 14561 (2002), the batch 23051 of the product ***„DÜRR SYSTEM-HYGIENE ID 213 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 % 15 minutes
1.0 % 30 minutes
0.5 % 60 minutes.

g) Hamburg, 04.02.2005, Dr. Holger Brill

ID213の希釈中和法を用いた定量的浮遊試験における殺真菌性

Pfor.We/ku 2005/01/05

ID213 fungicidal activity of chemical disinfectants for instruments prEN 14562 Candida albicans

ID213の殺真菌力評価のために、医療領域における定量的浮遊試験をカンジダ・アルビカンスに対して標準硬度の30±1℃の水を使用し、4.0%・2.0%・1.0%の3種の濃度にて1分・5分・15分・30分・60分の作用時間で評価を行った結果、真菌（カンジダ・アルビカンス）汚染状況下（0.3%ヒツジ赤血球+0.3%牛アルブミン）においてID213（1.0%濃度）は5分間の作用時間で十分な有効性を示した。

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2005-01-05
Prof. We/ku

DÜRR SYSTEM-HYGIENE ID 213
Quantitative carrier test - fungicidal activity of chemical disinfectants for instruments – prEN 14562 – Candida albicans
(phase2, step2)

TESTREPORT

Identification of the test laboratory:	SN 4137
Test product:	WF-312
Batch number:	Ch.-B.: 25138
Manufacturer:	Orochemie
Date of delivery:	2004-10-08
Date of order:	2004-10-04
Storage conditions:	those of the manufacturer
Product diluent recommended by the manufacturer for use:	tap water
Appearance:	clear, green liquid
Odour:	aromatic
Active substances:	per 100 g: 15 g 3-Aminopropyl-dodecyl-1,3-propandiamin, 12.5 g Alkyl-benzyl-dimethyl-ammoniumchlorid

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test method:	prEN 14562 (Nov 2002) Quantitative carrier test for evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area (phase 2, step2)
inactivation method:	dilution-neutralisation
period of analysis:	2004-12-03 to 2004-12-05
diluent used for product test solution:	water of standardized hardness
test temperature:	20 °C ± 1 °C
Product test concentrations:	4.0%, 2.0%, 1.0% (endconcentrations v/v)
contact times:	1min., 5min., 15 min., 30 min., 60min.
interfering substances:	3,0g/l bovine albumin + 3,0ml/l sheep erythrozytes (dirty conditions)
stability and appearance of the mixture during the procedure:	no precipitate or flocculent
counting procedure:	surface spread plate
incubation:	30 °C ± 1 °C – 48h
neutralizer or rinsing liquid:	3.0 % polysorbate 80 + 3.0 % saponine + 0.1 % histidine + 0.1 % cysteine
test organisms:	*Candida albicans* ATCC 10231

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Conclusion: According to prEN 14562 (11/2002), the batch Ch.-B.: 25138 of product DÜRR SYSTEM-HYGIENE ID 213 possesses a yeasticidal activity under dirty conditions for the referenced strain *Candida albicans* in 5 minutes when diluted at 1.0% (v/v) in hard water.

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

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

Kathrin Naujox
Department manager

ID213の希釈中和法を用いた定量的浮遊試験における殺真菌性

Dr.Rer Nat Holger Brill 2004/05/21

Determination of fungicidal effect of ID213 Instrument disinfection according to EN14562:2003

ID213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ウス・ニガーに対して標準硬度の30±1℃の水を用いて本液を、0.125%・0.25%・0.5%・1.0%の4種の濃度にて希釈し5分・15分・30分・60分の作用時間で評価を行った結果、真菌（カンジダ・アルビカンス及びアスペルギウス・ニガー）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ID213はそれぞれ以下の濃度と作用時間で十分な有効性を示した。
カンジダ・アルビカンス　1.0% 5分、0.5% 15分、0.25% 30分、0.125% 60分　アスペルギウス・ニガー　1.0% 60分

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Determination of fungicidal effect of

DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion according to EN 14562: 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 the sample

• Name of product:	DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion
• Batch number:	23051
• Manufacturer:	orochemie Dürr + Pflug GmbH & Co. KG, Kornwestheim
• Date of supply:	21.05.2004
• Storage conditions:	room temperature and darkness
• Appearance of product and its dilutions:	clear, bluegreen solution
• Odour:	aromatic, fresh
• pH value, concentrate:	11.1
• pH value, 1 %:	9.0
• Recommended diluent:	potable drinking water
• Active agents and concentration:	15.0 g 3-aminopropyl-dodecyl-1,3-propandiamine 12.5 g alkyl-benzyl-dimethyl-ammonium chloride

c) Test procedure and its validation

• Test procedure:	Quantitative carrier test (phase 2/step 2)
• Method:	Dilution-neutralisation method
• Neutraliser:	30 g/L polysorbate 80; 30 g/L saponin; 1 g/L histidine; 1 g/L cysteine (TSHC)

d) Test conditions

– Period of testing:	01.03.2005 to 31.03.2005	
– Product diluent:	sterile water of standardised hardness, 300 mg/kg $CaCO_3$	
– Product test concentrations:	0.125; 0.25; 0.5; 1.0 % volume concentration	
– Exposure times:	5, 15, 30, 60 minutes	
– Test temperature:	20°C ± 1°C	
– Organic load, high:	3 g/L sheep erythrocytes + 3 g/L bovine serum albumine	
– Incubation temperature:	30°C ± 1°C	
– Identification of the microbial strains used:	Candida albicans	ATCC 10231
	Aspergillus niger	ATCC 16404

e) Test results

The test results are summarised in table 1.

f) Conclusions

In accordance with prEN 14562 (2003), the batch 23051 of the product ***„DÜRR SYSTEM-HYGIENE ID 213 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 germs tested Candida albicans and Aspergillus niger. The following concentration-time relationships proved to be sufficiently effective against Candida albicans:

1.0 %	**5 minutes**
0.5 %	**15 minutes**
0.25 %	**30 minutes**
0.125 %	**60 minutes.**

The following concentration-time relationship proved to be sufficiently effective against Aspergillus niger:

1.0 %	**60 minutes.**

g) Hamburg, 07.04.2005, Dr. Holger Brill

ID213の希釈中和法を用いた定量的浮遊試験における殺結核菌（マイコバクテリウム）性

Dr.Rer Nat Holger Brill 2004/05/21

ID213 Instrument disinfection quantitative carrier test prEN14563 tuberculocidal activity

ID213の希釈中和法を用いた殺結核菌力評価のために、医療領域における定量的浮遊試験をマイコバクテリウムに対して標準硬度の36±1℃の水を用いて本液を、4.0%・2.0%・1.0%の3種の濃度にて希釈し15分・30分・60分の作用時間で評価を行った結果、ID213（2.0%濃度）は結核菌（マイコバクテリウム）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60分間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 213 Instrumentendesinfektion
quantitative carrier test
prEN 14563 – tuberculocidal activity
(phase 2, step 2)

TEST REPORT

Identification of the test laboratory:	SN 4137
Test product:	DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion
Batch number:	25138 (WF-312)
Manufacturer:	orochemie
Date of order:	2004-10-04
Date of delivery:	2004-10-08
Storage conditions:	those of the manufacturer
Product diluent recommended by the manufacturer for use:	tap waterr
Appearance:	clear, green liquid
Odour:	aromatic
Active substances per 100 g:	15 g 3-Aminopropyl-dodecyl-1,3-propandiamine, 12.5 g Alkyl-benzyl-dimethyl- ammoniumchloride

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test method:	**prEN 14563 (Nov 2002) Quantitative carrier test for evaluation of mycobactericidal activity of chemical disinfectants for instruments used in the medical area (phase 2, step 2)**
inactivation method:	dilution-neutralisation
period of analysis:	2005-01-24 to 2005-02-14
diluent used for product test solution:	water of standardized hardness
test temperature:	20 °C ± 1 °C
product test concentrations:	4.0%, 2.0%, 1.0% (end concentrations v/v)
contact times:	15 min., 30 min., 60min.
interfering substances:	0.3 % bovine albumin + 0.3 % sheep erythrocytes (dirty conditions)
stability and appearance of the mixture during the procedure:	no precipitate or flocculent
counting procedure:	spread plate method
incubation:	36 °C ± 1 °C – 21 d
neutralizer or rinsing liquid:	1.0 % polysorbate 80 + 3.0 % saponine + 0.1 % histidine + 0.5 % sodium thiosulphate (NMII)
test strain:	*Mycobacterium terrae* ATCC 15755

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Conclusion: According to prEN 14563 (11/2002), the batch 25138 of product DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion possesses a tuberculocidal activity under dirty conditions (0.3 % bovine albumin + 0.3 % sheep erythrocytes) in 60 minutes for the referenced strain *Mycobacterium terrae* when diluted at 2.0% (v/v) in hard water.

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

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ID213の希釈中和法を用いた定量的浮遊試験における殺結核菌（マイコバクテリウム）性

Hygcen GmbH 2005/02/09

ID213 Instrument disinfection quantitative carrier test prEN14563 tuberculocidal activity

ID213の希釈中和法を用いた殺結核菌力評価のために、医療領域における定量的浮遊試験をマイコバクテリウムに対して標準硬度の36±1℃の水を用いて本液を、4.0%・2.0%・1.0%の3種の濃度にて希釈し5分・15分・30分・60分の作用時間で評価を行った結果、ID213（2.0%濃度）は結核菌（マイコバクテリウム）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60分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 213 Instrumentendesinfektion
quantitative carrier test
prEN 14563 – tuberculocidal activity
(phase 2, step 2)

TEST REPORT

Identification of the test laboratory:	SN 4137
Test product:	DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion
Batch number:	25138 (WF-312)
Manufacturer:	orochemie
Date of order:	2004-10-04
Date of delivery:	2004-10-08
Storage conditions:	those of the manufacturer
Product diluent recommended by the manufacturer for use:	tap water
Appearance:	clear, green liquid
Odour:	aromatic
Active substances per 100 g:	15.0 g 3-Aminopropyl-dodecyl-1.3-propandiamine, 12.5 g Alkyl-benzyl-dimethyl-ammoniumchloride

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HYGICEN® Centrum für Hygiene und medizinische Produktsicherheit GmbH

test method:	**prEN 14563 (Nov 2002) Quantitative carrier test for evaluation of mycobactericidal activity of chemical disinfectants for instruments used in the medical area (phase 2, step 2)**
inactivation method:	dilution-neutralisation
period of analysis:	2004-10-26 to 2004-11-16
diluent used for product test solution:	water of standardized hardness
test temperature:	20 °C ± 1 °C
product test concentrations:	4.0%, 2.0%, 1.0% (endconcentrations v/v)
contact times:	5 min., 15 min., 30 min., 60 min.
interfering substances:	0.3 % bovine albumin + 0.3 % sheep erythrocytes (dirty conditions)
stability and appearance of the mixture during the procedure:	no precipitate or flocculent
counting procedure:	spread plate method
incubation:	36 °C ± 1 °C – 21 d
neutralizer or rinsing liquid:	1.0 % polysorbate 80 + 3.0 % saponine + 0.1 % histidine + 0.5 % sodium thiosulphate (NMII)
test strain:	*Mycobacterium terrae* ATCC 15755

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Conclusion: According to prEN 14563 (11/2002), the batch 25138 of product DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion possesses a tuberculocidal activity under dirty conditions (0.3 % bovine albumin + 0.3 % sheep erythrocytes) in 60 minutes for the referenced strain *Mycobacterium terrae* when diluted at 2.0 % (v/v) in hard water.

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

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medizinische Produktsicherheit GmbH

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Manager of technical affairs

K. Naujox
Department manager

ID213の希釈中和法を用いた定量的浮遊試験における殺結核菌（マイコバクテリウム）性

Dr.Per.Nat.Holger Brill 2004/05/24

Determination of tuberculocidal effect of ID213 instrument disinfection according to EN 14563:2001

ID213の希釈中和法を用いた殺結核菌力評価のために、医療領域における定量的浮遊試験をマイコバクテリウムに対して標準硬度の36±1℃の水を用いて本液を、0.5%・1.0%・2.0%の3種の濃度にて希釈し30分・60分の作用時間で評価を行った結果、ID213は結核菌（マイコバクテリウム）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、30分間（2.0%濃度）または、60分間（1.0%）の作用時間で十分な有効性を示した。

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Determination of tuberculocidal effect of

DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion according to EN 14563: 2001

a) Identification of the test laboratory

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

b) Identification of the sample

• Name of the product:	DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion
• Batch number:	23051
• Manufacturer:	orochemie Dürr + Pflug GmbH & Co. KG, Kornwestheim
• Date of supply:	24.05.2004
• Storage conditions:	room temperature and darkness
• Appearance of product and its dilutions:	clear, blue green solution
• Odour:	aromatic, fresh
• Recommended diluent:	potable drinking water
• Active agents and concentration:	15.0 g 3-aminopropyl-dodecyl-1,3-propandiamine 12.5 g alkyl-benzyl-dimethyl-ammonium chloride

c) Test procedure and its validation

• Test procedure:	Quantitative carrier test with glass-germ carriers (phase 2/step 2)
• Method:	Dilution-neutralisation method
• Neutraliser:	30 g/L polysorbate 80; 30 g/L saponin; 1 g/L histidine; 5 g/L sodium thiosulphate in phosphate buffer (TSH-NT)

d) Test conditions

– Period of the testing:	24.11.2004 to 23.12.2004
– Product diluent:	sterile water of standardised hardness, 300 mg/kg $CaCO_3$
– Product test concentrations:	0.5; 1.0; 2.0 % volume concentration
– Exposure times:	30, 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 the microbial strains used:	Mycobacterium terrae ATCC 15755

e) Test results

The test results are summarised in table 1.

f) Conclusions

In accordance with prEN 14563 (2001), the batch 23051 of the product ***„DÜRR SYSTEM-HYGIENE ID 213 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 tuberculocidal effect with regard to the test germ Mycobacterium terrae. The following concentration-time relationships proved to be sufficiently effective:

2.0 % 30 minutes
1.0 % 60 minutes.

g) Hamburg, 05.01.2005, Dr. Holger Brill

ID213の殺菌効力の検証

Dr.Ojajarvi Helsinki University 1994/10/12

Determination of tuberculocidal effect of ID213 instrument disinfection according to EN 14563:2001

ID213の殺菌効力の検証のために、有効濃度推定試験を黄色ブドウ球菌、腸内連鎖球菌、緑膿菌に対してWHO規定の標準硬水（300ppm以下）を用いて本液を、1.0%・1.5%・2.0%・3.0%の4種の濃度にて希釈しKelsey法を用いて評価を行った結果、ID213は有機負荷のない条件下（清潔環境）においては0.25%、有機負荷汚染状況下（汚染環境）においては0.5%の濃度で十分な有効性を示した。

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October 12, 1994

DÜRR SYSTEM-HYGIENE
ID 213
Disinfection of instruments

Expertise
on the results of testing the disinfecting strength of the ID 213 disinfectant

The substance to be examined was the liquid ID 213 disinfectant.
Its active disinfecting ingredients include 15% N-(3-aminopropyl) -N-dodekyl-1,3-propananidamine and 12.5% N-alkyl-N-benzyl-N,N-dimethyl ammonium 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% and 3%.

Results

The results are shown in the attached Table. In a clean environment the concentration required to kill the bacteria under examination was 0.25%. In a contaminated environment the corresponding concentration was 0.5%.

Enclosure: 1 Table

Helsinki, 12th October 1994.

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

ID213の菌及び真菌（C.アルビカンス）による高有機負荷条件下での使用期間の検証

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

Examination to determine the standing time of ID213 with high organic load(blood)

DGHMのガイドラインに従い、診療環境を想定した高有機負荷条件下（血液付着の多い条件）でのID213希釈液の使用期間の検証を黄色ブドウ球菌、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、ID213（2.0%濃度）は血液汚染が2%を超えない限り、最長14日間まで使用可能であることが検証された。ただし、本希釈液への0.5%の血液の混入は本来汚染と考えられるため、可能な限り早急に本液を交換することが推奨される。

27.11.2006
WF

DÜRR SYSTEM-HYGIENE
ID 213
Instrument Disinfection

Examination to determine the standing time of ID 213 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 213 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.

A **standing time of max. 14 days of the 2% ID 213 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 much earlier on account of its appearance – irrespective of the possibly prolonged standing time.

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

Dr. rer. nat. D. Heermann

ID213の超音波洗浄器使用時の菌及び真菌（C.アルビカンス）への効力の検証

Dr.rer.Nat.K-M.Wolf and Dr.rer.nat.D.Heermann 2008/01/29

Investigation into the activity of ID213 when using the ultrasonic cleaner

DGHMのガイドラインに従い、診療環境を想定したID213の超音波洗浄器使用時の効力の検証を黄色ブドウ球菌、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、ID213（2.0%濃度）は超音波洗浄器の使用により、作用時間を2分間に短縮することが可能であることが検証された。

DESINFEKTION · HYGIENE · FOTOCHEMIE

orochemie

29.01.2008
WF

DÜRR SYSTEM-HYGIENE
ID 213
Instrument Disinfection

Investigation into the activity of ID 213 when using the ultrasonic cleaner Dürr Hygosonic

The activity of ID 213 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 213 could be reduced by using ultrasonic equipment. A 2% ID 213 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 213 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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QUALITÄTS-MANAGEMENT
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ID213の超音波洗浄器使用時の菌及び真菌（C.アルビカンス）への効力の検証

Dr.rer.Nat.K-M.Wolf and Dr.rer.nat.D.Heermann 2006/12/01

Investigation into the activity of ID213 when using the ultrasonic cleaner

DGHMのガイドラインに従い、診療環境を想定したID213の超音波洗浄器使用時の効力の検証を黄色ブドウ球菌、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、ID213（2.0%濃度）は超音波洗浄機の使用により、作用時間を2分間に短縮することが可能であることが検証された。

01.12.2006
WF

DÜRR SYSTEM-HYGIENE
ID 213
Instrument Disinfection

Investigation into the activity of ID 213 when using an ultrasonic cleaner

The activity of ID 213 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 213 could be reduced by using ultrasonic equipment. A 2% ID 213 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 213 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

ID213の超音波洗浄器使用時の結核菌（マイコバクテリウム）への効力の検証

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の超音波洗浄器使用時の殺結核菌力評価のために、医療領域における定量キャリアー試験をマイコバクテリウムに対して行った結果、ID213（2.0%濃度）は結核菌（マイコバクテリウム）対して30分間の作用時間で十分な有効性を示した。

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Mr Dr. K.-M. Wolf
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Hamburg, 11 October 2007

Expert's report

Suitability of DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion for instrument disinfection using ultrasound (tuberculocidal effect according to DIN EN 14563:2002)

The disinfectant **DÜRR SYSTEM-HYGIENE ID 213 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 methods and requirements (phase 2/step 2)".

According to test report no. L 07/029 from Dr. Brill + Partner GmbH, **DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion** showed under high organic load using ultrasound a tuberculocidal activity.

DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion fulfils the requirements of the norm (RF ≥ 4) by the following concentration-time relation:

2.0 % **30 minutes.**

Dr Holger Brill

ID213のワクシニアウイルス不活性化効力の検証

Dr.H Brill Dr Brill+Partner GmbH 1993/03/24
Testing the virus-inactivating effectiveness of ID213

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、ID213のエンベロープ（被膜性）ワクシニアウイルスに対する不活性化効力の試験を行った結果、ID213(2.0%濃度)はエンベロープワクシニアウイルスに対してタンパク質負荷の有無に関わらず1分間の作用時間で十分な有効性を示した。

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March 24, 1993 Dr.St/W

DÜRR SYSTEM-HYGIENE

ID 213
Instrument Disinfection

Expertise

on the results of testing the virus-inactivating effectiveness of DÜRR SYSTEM-HYGIENE ID 213 Instrument Disinfection

The virucidal activity of the chemical disinfectant ID 213 on the **enveloped Vaccinia Virus** was examined in accordance with the guidelines of the Federal Health Department (BGA) and the German Association for the Control of Viral Diseases (DVV).

The reduction factor by four powers of ten required in the guidelines was achieved after only one minute contact time with the 2 % solution of ID 213.This goes for the preparation both with or without protein load.

As a result of our findings and in order to achieve a reliable virucidal activity with ID 213, the following instructions for use are provided:

Inactivation of the enveloped Vaccinia Virus:

2.0 % solution 1 minute contact time

(Dr. J. Steinmann)

ID213の牛ウイルス性下痢ウイルス（BVDV）への効力の検証

Dr.Jochen Steinmann 2001/09/24
BVDV efficacy of ID213

連邦健康管理局（BGA）及びウイルス病管理のためのドイツ協会（DVV）のガイドラインに従い、ID213の牛ウイルス性下痢ウイルス（BVDV）に対する定量的浮遊試験をC型肝炎ウイルスに対して本液を2.0%に希釈し、0.5分・1分・2分・5分の作用時間で評価を行った結果、ID213(2.0%濃度)は牛ウイルス性下痢ウイルス（BVDV）に対して30秒間の作用時間で十分な有効性を示した。

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BVDV efficacy of DÜRR SYSTEM-HYGIENE ID 213 INSTRUMENTENDESINFEKTION

EXPERT'S INVESTIGATION REPORT

The virucidal efficacy of the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 213 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 213 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 213 INSTRUMENTENDESINFEKTION for the inactivation of BVDV as follows:

2.0 % 30 seconds

Dr. J. Steinmann

ID213のアデノウイルスへの不活性化効力の検証

Dr.Jochen Steinmann 1993/04/22

Testing the virus-inactivating effectiveness of ID213

連邦健康管理局（BGA）及びウイルス病管理のためのドイツ協会（DVV）のガイドラインに従い、ID213のアデノウイルスに対する不活性化効力の試験を行った結果、ID213(2.0%濃度)はアデノウイルスに対してタンパク質負荷の有無に関わらず30分間の作用時間で十分な有効性を示した

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April 22, 1993
Dr.St/W

DÜRR SYSTEM-HYGIENE

ID 213
Instrument Disinfection

Expertise

on the results of testing the virus-inactivating effectiveness of DÜRR SYSTEM-HYGIENE ID 213 Instrument Disinfection

The virucidal activity of the chemical disinfectant ID 213 on the **Adeno Virus** was examined in accordance with the guidelines of the Federal Health Department (BGA) and the German Association for the Control of Viral Diseases (DVV).

The reduction factor by four log orders required in the guidelines was achieved after 30 minutes contact time with the 2.0 % solution of ID 213. This goes for the preparation both with or without protein load.

As a result of our findings and in order to achieve a reliable virucidal activity with ID 213, the following instructions for use are provided:

Inactivation of the Adeno Virus:

2.0 % solution 30 minutes contact time

(Dr. J. Steinmann)

ID213のポリオーマウイルスSV40 への不活性化効力の検証

Dr.Jochen Steinmann 1993/04/22
Polyomavirus SV 40 efficacy of ID213 in a quantitative suspension test at 20 degree

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、ID213の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本液1.0%・2.0%の2種の濃度にて20℃で希釈し5分・10分・15分・30分・60分・120分・240分の作用時間で行った結果、ID213はポリオーマウイルスSV40に対して30分（1.0%濃度）、5分（2.0%）の作用時間で十分な有効性を示した。。

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2005-11-19
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Polyomavirus SV 40 efficacy of DÜRR SYSTEM-HYGIENE ID 213 INSTRUMENTEN-DESINFEKTION in a quantitative suspension test at 20°C

EXPERT OPINION

The virus-inactivating properties of the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 213 INSTRUMENTENDESINFEKTION of orochemie against polyomavirus SV 40 strain 777 were investigated by a quantitative suspension test according to the guideline of the Bundesgesundheitsamt (BGA, Federal Office of Health, now Robert Koch-Institut) and the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (German Association for the Control of Virus Diseases).
According to this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$ (inactivation ≥ 99.99%).

DÜRR SYSTEM-HYGIENE ID 213 INSTRUMENTENDESINFEKTION was examined as 1.0% and 2.0% solution at 20°C. The exposure times were 5, 10, 15, 30, 60, 120 and 240 minutes. After an exposure time of 5 (2.0%) and 30 (1.0%) minutes virus reduction exceeded 4 $\log_{10}$-steps in all assays. Due to the lack of guidelines simulating practical conditions, results of the quantitative suspension test lead to the recommendation to use the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 213 INSTRUMENTEN-DESINFEKTION for inactivation of polyomavirus SV 40 as follows:

1.0%	**30 minutes**
2.0%	**5 minutes**

Dr. J. Steinmann

ID213のポリオⅠ型ウイルス への不活性化効力の検証

Dr.Jochen Steinmann 1993/06/10

Testing the virus-inactivating effectiveness of ID213

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、ID213のポリオウイルスⅠ型に対する不活性化効力の試験を行った結果、ID213(6.0%濃度)はポリオウイルスⅠ型に対してタンパク質負荷の有無に関わらず240分間の作用時間で十分な有効性を示した。

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June 10, 1993 Dr.St/W

DÜRR SYSTEM-HYGIENE

ID 213
Instrument Disinfection

Expertise

on the results of testing the virus-inactivating effectiveness of DÜRR SYSTEM-HYGIENE ID 213 Instrument Disinfection

The virucidal activity of the chemical disinfectant ID 213 on the **Polio Virus, Type I, Parent Mahoney/Pette** was examined in accordance with the guidelines of the Federal Health Department (BGA) and the German Association for the Control of Viral Diseases (DVV).

The reduction factor by four powers of ten required in the guidelines was achieved after 240 minutes contact time with the 6,0 % solution of ID 213. This goes for the preparation both with or without protein load.

As a result of our findings and in order to achieve a reliable virucidal activity with ID 213, the following instructions for use are provided:

Inactivation of the Polio Virus, Type I:

6.0 % solution **240 minutes contact time**

(Dr. J. Steinmann)

ID213のポリオーマウイルス不活性化効力の検証

Dr.Olaf Thraenhart University Clinic Essen 1994/09/02
Testing the virucidal effectiveness of ID213 on the naked Polio 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、ID213のノンエンベロープ（非被膜性）ポリオーマウイルスに対する不活性化効力の浮遊試験をタンパク負荷無し及びタンパク負荷有り（10%牛胎児血清+0.2%牛血清アルブミン）行った結果、ID213(10%濃度)はノンエンベロープポリオーマウイルスに対して120分間の作用時間で十分な有効性を示した。ただし、高タンパク質の有機負荷により効能性が阻害される可能性がある場合、必要に応じて作用時間を延長すること。

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September 2, 1994

DÜRR SYSTEM-HYGIENE
ID 213
Instrument Disinfection

Expertise

on the results of testing the virucidal effectiveness of the chemical disinfectant ID 213 on the naked Polio virus

1. **Identification of test sample**

Name:	DÜRR SYSTEM-HYGIENE ID 213 Instrument Disinfection
Application:	Disinfection of instruments
Manufacturer:	OROCHEMIE Dürr + Pflug GmbH + Co KG, Kornwestheim
Storage conditions:	Room temperature
Active substances:	Trialkylamine and a quaternary ammonium compound

2. **Examination conditions**

Examination period:	1994
Disinfectant concentration:	10 volume %
Contact times:	5, 30, 60, 120 minutes
Contact temperature:	+ 20 °C
Test virus according to BGA/DVV guidelines	Polio virus
Protein loads:	Without, 10 % foetal calf serum (FCS) 0.2 % bovine serum albumin (BSA) according to BGA/DVV guidelines
Testing method:	Suspension test according to BGA/DVV guidelines

4. **Test results** Table 1 and illustration 1 (the complete test report has 11 pages)

A virus inactivation by log $_{10}ID_{50}$>4.0 was achieved in the test strains without protein load and with the addition of serum. In one out of two test strains with bovine serum albumin, a virus inactivation by log $_{10}ID_{50}$>4.0 was detected, whereas the other test strain showed a virus inactivation by log $_{10}ID_{50}$>3.6.

5. **Assessment**

In order to achieve a reliable virucidal activity with ID 213 against the polio virus, the following instructions for use are provided:

Disinfectant concentration: 10 % Exposure time: 120 minutes

The effectiveness of the disinfectant might be inhibited by a high protein load. In that case, the exposure time should be prolonged, if necessary.

(Dr. O. Thraenhart, Academic Director)

ID213のアデノウイルスへの効力の検証

Dr.Jochen Steinmann Mikrolab GmbH 2006/08/22
Effectiveness of ID213 against adeno-virus according to EN14476:2005

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、ID213のアデノウイルスに対する定量的浮遊試験をアデノウイルス5型に対して本液を2.0%に希釈し、5分・15分・30分・60分の作用時間で評価を行った結果、ID213(2.0%濃度)はアデノウイルス5型に対して60分間の作用時間で十分な有効性を示した。

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Effectiveness of DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion against adeno-virus according to EN 14476:2005

EXPERT OPINION

Effectiveness of the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion 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 213 Instrumentendesinfektion was examined as 2.0% solution. The exposure times were 5, 15, 30 and 60 minutes.

After 30 (dirty conditions) and 60 (clean conditions) min exposure time a reduction factor of ≥ 4.50 was measured.

Therefore, summarizing the results of the experiments it can be declared that the disinfectant DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion is virucidal against adenovirus type 5 with the following conditions:

2.0% **60 minutes**

Dr. J. Steinmann

ID213のポリオウイルス

Dr.Jochen Steinmann Mikrolab GmbH 2006/08/22
Effectiveness of ID213 against polio-virus according to EN14476:2005

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、ID213のポリオウイルスに対する定量的浮遊試験をポリオウイルスⅠ型に対して本液を、6.0%・8.0%・10.0%の3種の濃度にて希釈し、30分・60分・120分・240分の作用時間で評価を行った結果、ID213(8.0%濃度)はポリオウイルスⅠ型に対して240分間の作用時間で十分な有効性を示した。

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Effectiveness of DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion against polio-virus according to EN 14476:2005

EXPERT OPINION

Effectiveness of the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion of orochemie was investigated against poliovirus type 1 under dirty conditions 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 213 Instrumentendesinfektion was examined as 6.0 %, 8.0 % and 10.0 % solution. The exposure times were 30, 60, 120 and 240 minutes. After 240 min exposure time a reduction factor of ≥ 4.00 was measured (8.0 %).

Therefore, summarizing the results of the experiments it can be declared that the instrument disinfectant DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion is virucidal against poliovirus type 1 with the following conditions:

8.0 % **240 minutes**

Dr. J. Steinmann

ID213のラットへの急性経口毒性試験

Dr.rer.nat.E.Bien IBR Forschungs GmbH 1993/07/05
Effectiveness of ID213 against polio-virus according to EN14476:2005

OECDのガイドラインに従い、ID213の急性経口毒性試験をウィスターラット（オスまたはメス5匹及びメス5匹のみの3グループ）に対して行い、各ラットに対し本液（原液）を1000mg／Kg（グループ1）・1500mg／Kg（グループ2）・2000mg／Kg（グループ3）、一回投与した結果、オスでは24時間で>1500.0mg／Kg、メスでは1508.5mg／Kgが致死量とされ、14日間ではオスでは約1417.0mg／Kg、メスでは1257.6mgが致死量であることが判明し、ID213（原液）の誤飲は人体に有害であることが証明された。

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July 5, 1993

Project No.: 10-04-2467/00-93

DÜRR SYSTEM-HYGIENE

ID 213
Instrument Disinfection

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

I. INTRODUCTION AND AIM

The aim of the test was to determine the acute median lethal dose of ID 213. Information derived from this test serves to indicate the existence of possible hazards likely to arise from short-term exposure to the test article by the oral route.

The test was conducted according to the OECD guideline for the testing of chemicals OECD 402 (February 24, 1987) and to the EEC directive 84/449 EEC (September 19, 1984). The study was carried out as described in the corresponding protocol approved by the testing facility and the study sponsor on February 4 and February 15, 1993, respectively. The Principles of Good Laboratory Practice for the testing of chemicals as specified by the national (BGBl. I, No. 13, § 19 a, March 22, 1990) and international (OECD, Paris, 1982) legislation were followed during the performance of the study.

II. SUMMARY

The acute oral toxicity of ID 213 was investigated in 3 groups of Wistar rats, containing 5 males and 5 females or 5 females only (Group III).

On the basis of the range finding results, the animals were given a single oral administration of ID 213 at doses of 1000 mg/kg (group I), 1500 mg/kg (group II) and 2000 mg/kg (group III).

Clinical observations were conducted at regular intervals during the 14-day observation period. Body weights were measured at days 0, 7 and 14 p.a. Gross pathological examinations were performed immediately on animals found dead or killed in extremis and at termination on surviving animals. LD_{50} values were determined after 24 hours and 14 days.

The following results were obtained:

1. 12 of 25 animals died pre-terminally
2. Dose-dependent clinical signs were observed up to 4 days p.a. The most striking findings were apart from the poor general condition abnormal gait, abnormal body posture, increased salivation, diarrhea and increased diuresis.
3. Weight gains were normal in the surviving animals.
4. Gross pathological examinations at 14 days p.a. (terminal necropsy) revealed no test article-dependent findings apart from alterations in the stomach in one animal. However, animals found dead showed alterations, e.g. in the stomach, the intestinal tract and the kidney which were considered to be test-article related.
5. The following LD_{50} values were determined after 24 hours and 14 days:

	24 hours	**14 days**
male	**> 1500.0 mg/kg**	**approx. 1417.0 mg/kg**
female	**1508.5 mg/kg**	**1257.6 mg/kg**

6. According to the EEC directive 91/325/EEC and the Gefahrstoffverordnung (GefStoffV), 1987 (BGBl. Federal Gazette I, page 2721), the test article

"DÜRR SYSTEM-HYGIENE ID 213 Instrument Disinfection"

is classified as **"harmful".**

(PD Dr. rer. nat. E. Bien,
Study Director)

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July 1993 / ha

FINAL REPORT

Acute Oral Toxicity Test of
"Dürr-System-Hygiene
ID 213
Instrumentendesinfektion"
in Rats
Project No.: 10-04-2467/00-93

Study Sponsor:
Orochemie
Dürr + Pflug GmbH + Co. KG
Enzstraße 20

70806 Kornwestheim

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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.

PD Dr. rer. nat. E. Bien .....

Study Director

5.7.93

Date

I. INTRODUCTION AND AIM

The aim of the test was to determine the acute median lethal dose of **"Dürr-System-Hygiene ID 213 Instrumentendesinfektion"**. Information derived from this test serves to indicate the existence of possible hazards likely to arise from short-term exposure to the test article by the oral route.

The test was conducted according to the OECD guideline for the testing of chemicals OECD 401 (February 24, 1987) and to the EEC directive 84/449 EEC (September 19, 1984). The study was carried out as described in the corresponding protocol approved by the testing facility and the study sponsor on February 4 and 15, 1993, respectively. The principles of Good Laboratory Practice for the testing of chemicals as specified by national (BGBl. I, no. 13, § 19 a, March 22, 1990) and international (OECD, Paris, 1982) legislation were followed during the performance of the study.

II. SUMMARY

The acute oral toxicity of **"Dürr-System-Hygiene ID 213 Instrumenten-desinfektion"** was investigated in 3 groups of Wistar rats, containing 5 males and 5 females or 5 females only (Group III).

On the basis of the range finding results, the animals were given a single oral administration of **"Dürr-System-Hygiene ID 213 Instrumentendesinfektion"** at doses of 1000 mg/kg (group I), 1500 mg/kg (group II) and 2000 mg/kg (group III).

Clinical observations were conducted at regular intervals during the 14-day observation period. Body weights were measured at days 0, 7 and 14 p.a. Gross pathological examinations were performed immediately on animals found dead or killed in extremis and at termination on surviving animals. LD_{50} values were determined after 24 h and 14 days.

The following results were obtained:

1. 12 of 25 animals died pre-terminally.

2. Dose-dependent clinical signs were observed up to 4 days p.a. The most striking findings were apart from the poor general condition abnormal gait, abnormal body posture, increased salivation, diarrhea and increased diuresis.

3. Weight gains were normal in the surviving animals.

4. Gross pathological examinations at 14 days p.a. (terminal necropsy) revealed no test article-dependent findings apart from alterations in the stomach in one animal. However, animals found dead showed alterations, e.g. in the stomach, the intestinal tract and the kidney which were considered to be test article-related.

5. The following LD_{50} values were determined after 24 h and 14 days:

	24 h	**14 days**
male	**> 1500.0 mg/kg**	**approx. 1417.0 mg/kg**
female	**1508.5 mg/kg**	**1257.6 mg/kg**

6. According to the EEC directive 91/325/EEC and the Gefahrstoffverordnung (GefStoffV), 1987 (BGBl. I, p. 2721), the test article

   "Dürr-System-Hygiene ID 213 Instrumentendesinfektion"

   is classified as **"harmful"**.

I B R Forschungs GmbH
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April 15, 1993

Project No.: 10-04-2468/00-93

DÜRR SYSTEM-HYGIENE

ID 213
Instrument Disinfection

Expertise
on the results of testing the acute dermal toxicity in rats in conformity with the OECD guidelines

I. INTRODUCTION AND AIM

The aim of the test was to determine the acute median lethal dose of ID 213. Information derived from this test serves to indicate the existence of possible hazards likely to arise from short-term exposure to the test article by the dermal route.

The test was conducted according to the OECD guideline for the testing of chemicals OECD 402 (February 24, 1987) and to the EEC directive 84/449 EEC (September 19, 1984). The study was carried out as described in the corresponding protocol approved by the testing facility and the study sponsor on February 4 and February 15, 1993, respectively. The Principles of Good Laboratory Practice for the testing of chemicals as specified by the national (BGBl. I, No. 13, § 19 a, March 22, 1990) and international (OECD, Paris, 1982) legislation were followed during the performance of the study.

II. SUMMARY

The acute dermal toxicity of ID 213 was investigated in 5 male and 5 female Wistar rats. Due to the extreme skin reactions after application of the pure test article, a 2 % solution was investigated.

On the basis of the range finding results, each animal was given a single dermal administration of ID 213 at a dose of 2000 mg/kg body weight. The skin was exposed to the test article for 24 hours and signs of erythema and oedema were subseequently evaluated once daily for 14 days.

Clinical observations were conducted at regular intervals during the 14-day observation period. Body weights were measured at days 0, 7 and 14 p.a. Gross pathological examinations were performed on animals at termination.

The following results were obtained:

1. No abnormal clinical signs were observed.
2. No signs of erythema or oedema were observed.
3. Weight gains were normal in all animals.
4. Gross pathological examinations at 14 days p.a. (terminal necropsy) revealed no test article-dependent findings.
5. According to the requirements of the limit test, the LD_{50} values after 24 hours and 14 days were as follows:

   male and female **> 2000 mg/kg**

6. The above value is higher than the limit specified as harmful by the EEC directive 91/325/EEC and the Gefahrstoffverordnung (GefStoffV), 1987 (BGBl. Federal Gazette I, page 2721). When applied to the skin, a 2 % solution of the test article

   "DÜRR SYSTEM-HYGIENE ID 213 Instrument Disinfection"

   may therefore be classified as **"non-toxic"**.

(PD Dr. rer. nat. E. Bien,
Study Director)

ID213のラットへの急性経皮毒性試験

Dr.rer.nat.E.Bien IBR Forschungs GmbH 1993/07/05
Acute Oral Toxicity Test of ID213 in Rats

OECDのガイドラインに従い、ID213の急性経皮毒性試験をウィスターラット（5匹のオスまたはメス）に対して行い、各ラットに対し本液（2.0%濃度）を2000mg／Kg経皮投与しラットの皮膚を試験品に24時間暴露した際の、紅斑及び浮腫のみの兆候を14日間に渡り検査した結果、オス・メスともに24時間または14日間の致死量は>2000mg／Kgであることが判明した。この量はEECが定める上限を超えているため、ID213（2.0%濃度）の希釈液の人体皮膚への接触は無毒であることが証明された。

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April 1993 / ha

FINAL REPORT

Acute Dermal Toxicity Test of
"DÜRR-SYSTEM-HYGIENE ID 213 Instrumentendesinfektion"
in Rats
Project No.: 10-04-2468/00-93

Study Sponsor:
Orochemie
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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.

PD Dr. rer. nat. E. Bien .....Bien.....

Study Director

15.4.93

Date

I. INTRODUCTION AND AIM

The aim of the test was to determine the acute median lethal dose of **"DÜRR-SYSTEM-HYGIENE ID 213 Instrumentendesinfektion"**. Information derived from this test serves to indicate the existence of possible hazards likely to arise from short-term exposure to the test article by the dermal route.

The test was conducted according to the OECD guideline for the testing of chemicals OECD 402 (February 24, 1987) and to the EEC directive 84/449/EEC (September 19, 1984). The study was carried out as described in the corresponding protocol approved by the testing facility and the study sponsor on February 4 and February 15, 1993, respectively. The principles of Good Laboratory Practice for the testing of chemicals as specified by national (BGB1. I, no 13, § 19 a, March 22, 1990) and international (OECD, Paris, 1982) legislation were followed during the performance of the study.

II. SUMMARY

The acute dermal toxicity of **"DÜRR-SYSTEM-HYGIENE ID 213 Instrumentendesinfektion"** was investigated in 5 male and 5 female Wistar rats. Due to the extreme skin reactions after application of the pure test article, a 2 % solution was investigated.

On the basis of the range finding results, each animal was given a single dermal administration of **"DÜRR-SYSTEM-HYGIENE ID 213 Instrumentendesinfektion"** at a dose of 2000 mg/kg body weight. The skin was exposed to the test article for 24 h and signs of erythema and oedema were subsequently evaluated once daily for 14 days.

Clinical observations were conducted at regular intervals during the 14-day observation period. Body weights were measured at days 0, 7 and 14 p.a. Gross pathological examinations were performed on animals at termination.

The following results were obtained:

1. No abnormal clinical signs were observed.

2. No signs of erythema or oedema were observed.

3. Weight gains were normal in all animals.

4. Gross pathological examinations at 14 days p.a. (terminal necropsy) revealed no test article-dependent findings.

5. According to the requirements of the limit test, the LD_{50} values after 24 h and 14 days were as follows:

   male and female **> 2000 mg/kg**

6. The above value is higher than the limit specified as harmful by the EEC directive 91/325/EEC and the Gefahrstoffverordnung (GefStoffV), 1987 (BGBl.I p. 2721). When applied to the skin, a 2 % solution of the test article

   "DÜRR-SYSTEM-HYGIENE ID 213 Instrumentendesinfektion"

   may therefore be classified as **"non-toxic"**.

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April 26, 1993

Project No.: 10-03-2469/00-93

DÜRR SYSTEM-HYGIENE

ID 213
Instrument Disinfection

Expertise

on the results of testing the acute eye irritation in rats in conformity with the OECD guidelines (Corrosion Test)

I. INTRODUCTION AND AIM

The aim of the test was to assess the irritant and/or corrosive effect(s) of ID 213 on the eyes and associated mucous membranes. Information derived from this test serves to indicate the existence of possible hazards likely to arise from exposure of the eyes to the test article.

The test was conducted according to the OECD guideline for the testing of chemicals OECD 405 (February 24, 1987) and to the EEC directive 84/449 EEC (September 19, 1984). The study was carried out as described in the corresponding protocol approved by the testing facility and the study sponsor on February 5 and February 15, 1993, respectively. The Principles of Good Laboratory Practice for the testing of chemicals as specified by the national (BGBI. I, No. 13, § 19 a, March 22, 1990) and international (OECD, Paris, 1982) legislation were followed during the performance of the study.

II. SUMMARY

The potential toxicity of ID 213 was assessed in an acute eye irritation/corrosion test on 6 Albino rabbits. In each animal, 0.1 ml of a 2 % solution of the test article was introduced into the conjunctival sac of one eye, the untreated eye serving as a control. Both eyes were examined at 1, 24, 48, 72 hours and at day 4. In animals numbers 2 to 6 observations were extended up to day 11.

Results

Ocular lesions of varying extent, severity and duration were apparent in all animals during the observation period. The observed findings were reversible within 4 to 11 days p.a.

Assessment

The test article was classified on the basis of the mean values of ocular reactions at 24, 48 and 72 hours p.a. According to the criteria specified by the EEC directive 91/325/EEC of March 1, 1991 and the Gefahrstoffverordnung (GefStoffV), 1987 (BGBl. Federal Gazette I, page 2721), when applied to the eye as a **2 % solution**, the test article

"DÜRR SYSTEM-HYGIENE ID 213 Instrument Disinfection"

may be classified as **"irritant".**

(Dr. med. vet. K. Kaufmann,
Study Director)

ID213のウサギへの急性眼刺激／腐食性試験

Dr.rer.nat.E.Bien IBR Forschungs GmbH 1993/04
Acute Oral Toxicity Test of ID213 in Rats

OECDのガイドラインに従い、ID213の急性眼刺激／腐食性試験を6匹のアルビノウサギに対して行い、本液（2.0%濃度）を0.1ml片眼の結膜嚢に点眼し、未処置の眼と比較し両眼の経過を1時間・24時間・48時間・72時間及び4日後に検査した。5匹のウサギへの経過観察は11日間まで延長し、経過観察中すべての検体において様々な程度・重症度の反応が現れたことから、ID213（2.0%濃度）は人体眼球への刺激物であることが証明された。

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April 1993 / bi

FINAL REPORT

Acute Eye Irritation / Corrosion Test of
"DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion"
in Rabbits
Project No.: 10-03-2469/00-93

Study Sponsor:
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Dürr + Pflug GmbH + Co. KG
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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.

Dr. med. vet. K. Kaufmann

Study director

26.4.93

Date

I. INTRODUCTION AND AIM

The aim of the test was to assess the irritant and/or corrosive effect(s) of **"DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion"** on the eyes and associated mucous membranes. Information derived from this test serves to indicate the existence of possible hazards likely to arise from exposure of the eyes to the test article.

The test was conducted according to the OECD guideline for the testing of chemicals (OECD 405, February 24, 1987) and to the EEC directive 84/449/EEC, September 19, 1984. The study was carried out as described in the corresponding protocol approved by the testing facility and the study sponsor on February 5 and 15, 1993, respectively. The principles of Good Laboratory Practice for the testing of chemicals as specified by national (BGB1. I, no 13, §19 a, March 22, 1990) and international (OECD, Paris, 1982) legislation were followed during the performance of the study.

II. SUMMARY

The potential toxicity of **"DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion"** was assessed in an acute eye irritation/corrosion test on 6 albino rabbits. In each animal, 0.1 ml of a 2 % solution of the test article was introduced into the conjunctival sac of one eye, the untreated eye serving as a control. Both eyes were examined at 1, 24, 48, 72 h and at day 4. In animals no. 2 - 6 observations were extended up to day 11.

Results

Ocular lesions of varying extent, severity and duration were apparent in all animals during the observation period. The observed findings were reversible within 4 - 11 days p.a.

Assessment

The test article was classified on the basis of the mean values of ocular reactions at 24, 48 and 72 h p.a. According to the criteria specified by the EEC directive 91/325/EEC of March 1, 1991 and the Gefahrstoffverordnung (GefStoffV), 1987 (BGBl. I, p. 2721), when applied to the eye as a 2 % solution, the test article

"DÜRR SYSTEM-HYGIENE ID 213 Instrumentendesinfektion"

may be classified as **irritant**.

ID213の原料適合性試験

Dr.rer.nat.K.-M.Wolf and Dr.rer.nat.D.Heermann 1993/11/23
Testing the material compatibility of ID213

ID213の原料適合性を検証するため、歯科用一般器具・外科用器具、歯科用回転器具及びアルミニウム製トレイそれぞれに試験を行った。

＜歯科用一般器具・外科用器具＞

室温環境で本液（2.0%濃度）に4週間浸漬し、期間中は1日置きで朝、本希釈液から器具を取り出し、水洗を行わずに自然乾燥させ再浸漬を繰り返した後、器具を水洗乾燥させ実態顕微鏡にて検査を行った結果、すべての器具に目に見える変化は認められず器具に対する優れた適合性を示した。

＜歯科用回転器具＞

室温環境で本液（2.0%濃度）に14日間浸漬し、期間中は毎朝、本希釈液から器具を取り出し、水洗を行わずに自然乾燥させ再浸漬を繰り返した後、すべてのドリル・リーマー・研磨器具等を水洗後、簡易乾燥させ実態顕微鏡にて検査を行った結果、回転器具を別容器に浸漬した後はすべての器具に目に見える変化は認められなかったが、アルミニウム製の根管処置器具にのみ試験開始1日後、わずかな変色が見られたが使用価値に問題はなかった。

＜アルミニウム製トレイ＞

他器具とは別に準備した本液（2.0%濃度）に14日間浸漬した結果、変色・剥がれを含む器具の変化は見られなかったことからID213はアルミニウム製トレイに対しても優れた適合性を示すことが証明された。

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DÜRR SYSTEM-HYGIENE

ID 213
Instrument Disinfection

Expertise
on the results of testing the material compatibility of ID 213

The aim of the test was to determine the material compatibility of ID 213 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 213 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 213 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 213 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 213 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 213 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 213 with aluminium trays can be assessed.

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