SC Johnson PROFESSIONAL
A Family Company®

Deb® InstantGEL **Complete**

Summary of Microbiological Test Data

ISSUE 4

deb SKIN CARE

About SC Johnson Professional

SC Johnson Professional® provides expert skin care, cleaning and hygiene solutions for industrial, institutional and healthcare users. It incorporates the Deb range of specialist occupational skin care products along with well-known SC Johnson brands and innovative professional cleaning and hygiene products.

Our purpose is to bring innovative, quality products and services to professional markets that rethink how people and organisations experience skin care, cleaning and hygiene, all under a single brand.

Industry

Food Processing & Food Service

Commercial

Healthcare

Contents

This brochure provides summary information on the microbiological test conducted on Deb® InstantGEL Complete.

Deb® InstantGEL **Complete**

Alcohol-Based Gel Hand Disinfectant

Bactericidal I Virucidal I Yeasticidal I Mycobactericidal

Deb® InstantGEL Complete is an alcohol-based hand sanitising gel containing purified Hamamelis extract, providing skin protection under gloves in addition to highly effective broad spectrum biocidal efficacy.

In vitro bactericidal **EN 1276**

Objective:

This European Standard is a quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas.

General Study Information	
Protocol:	EN 1276:2010
Test House:	Deb R&D Microbiology Dept, Krefeld, DE
Date of Report:	19th March 2018
Report Ref:	2018/155
Test Product:	Deb® InstantGEL Complete

Summary of Test Conditions	
Test Product:	Deb® InstantGEL Complete (M963.3)
Batch Number:	NW120103a_L
Product Test Concentrations:	80%, 50% and 20% (v/v end concentrations)
Diluent:	Distilled Water
Test Temperature:	20°C
Incubation Temperature:	36°C ± 1 °C
Neutraliser:	3.0% polysorbate 80, 3.0% saponine, 0.1% histidine, 0.3% lecithine, 0.5% sodium thiosulphate, 0.1% tryptone, 0.9% NaCl
Conditions:	Dirty
Interfering Substance:	3.0 g/l bovine albumin
Test Strains:	*Staphylococcus aureus ATCC 6538* *Escherichia coli ATCC 10536* *Enterococcus hirae ATCC 10541* *Pseudomonas aeruginosa ATCC 15442*
Contact Time:	30 seconds

Test Results:

All test bacteria were sufficiently (RF>5) inactivated with the following concentration-time relationship: dirty conditions, 80% (v/v), 30 seconds.

Study Conclusion:

According to DIN EN 1276:2010 (phase 2, step 1), Deb® InstantGEL Complete possesses bactericidal activity >5 log 99.999% in 30 seconds at 20˚C for the reference strains *Staphylococcus aureus, Enterococcus hirae, Escherichia coli* and *Pseudomonas aeruginos*a when diluted at 80% (v/v).

In vitro bactericidal **EN 13727**

Objective:

This European Standard is a quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the medical area.

General Study Information	
Protocol:	EN 13727:2015
Test House:	HygCen GmbH Schwerin, Germany
Date of Report:	15th March 2018
Report Ref:	SN 23593
Test Product:	Deb® InstantGEL Complete (NW120103a_L)
Study Dates:	02/03/18 – 04/03/18

Summary of Test Conditions	
Test Product:	Deb® InstantGEL Complete
Batch Number:	NW120103aL
Product Test Concentrations:	80%, 50% and 25% (v/v end concentrations)
Diluent:	Distilled Water
Test Temperature:	20°C
Incubation Temperature:	36°C ± 1°C
Neutraliser:	3.0% polysorbate 80, 3.0% saponine, 0.1% histidine, 0.1% cysteine (TSHC)
Conditions:	Clean
Interfering Substance:	0.3 g/l bovine albumin
Test Strains:	*Staphylococcus aureus ATCC 6538* *Escherichia coli NCTC 10538* *Enterococcus hirae ATCC 10541* *Pseudomonas aeruginosa ATCC 15442*
Contact Time:	30 seconds

Test Results:

All test bacteria were sufficiently (Log RF >5) inactivated with the following concentration-time relationship: clean conditions, 80% (v/v), 30 seconds.

Study Conclusion:

According to EN 13727 (phase 2, step 1), Deb® InstantGEL Complete possesses bactericidal activity >5 log (99.999%) in 30 seconds at 20˚C for all reference strains tested, including *Staphylococcus aureus, Enterococcus hirae, Escherichia coli* and *Pseudomonas aeruginosa* when diluted at 80% (v/v) and therefore satisfies the requirements of EN 13727:2015.

In vivo bactericidal **EN 1500**

Objective:

This European Standard specifies an *in vivo* test for assessing hygienic handrubs. The method of test simulates practical conditions for establishing whether a product for hygienic handrub reduces the release of transient flora when rubbed onto the artificially contaminated hands of volunteers. To meet the standard, test products must perform no worse than the reference product propan-2-ol.

General Study Information	
Protocol:	EN 1500:2013
Test House:	HygCen GmbH Schwerin, Germany
Date of Report:	19th December 2017
Report Ref:	SN 23593
Test Product:	Deb® InstantGEL Complete (NW120103a_L)
Study Dates:	21/11/17 – 09/12/17

Summary of Test Conditions	
Test Product:	Deb® InstantGEL Complete
Batch Number:	NW120103aL
Product Test Concentrations:	100% (Neat)
Test Strain:	*Escherichia coli* NCTC 10538
Exposure Time:	30 seconds
Neutraliser:	3.0 % polysorbate 80 + 3.0 % saponin + 0.1 % histidine + 0.1 % cysteine
Reference Procedure:	2 x 3ml 60% (v/v) propan-2-ol, rubbed onto the hands during 60 seconds
Test Procedure:	Rub the hands with 3ml of product Deb® InstantGEL Complete for 30 seconds

Test Results:

From the critical values for Wilcoxon`s matched-pairs signed-ranks test the entry for n=20 and a one-sided 0.025 level of significance the critical value of 52 is found - hence c = 52 + 1 = 53. The 53rd value is -0.17. Hence the Hodges-Lehmann upper one-sided 97.5% confidence limit for the difference in log reductions between reference and Deb® InstantGEL Complete is -0.17, which is less than the agreed inferiority margin of 0.6. Therefore, it can be concluded that Deb® InstantGEL Complete is non- inferior to the reference.

Study Conclusion:

The test product Deb® InstantGEL Complete is suitable for the hygienic hand rub according to EN 1500:2013 (phase 2, step 2) with the following application - Rub the hands with 3ml of product for 30 seconds.

In vivo bactericidal (Surgical Rub) **EN 12791**

Objective:

The European Standard for products to be used for surgical hand disinfection (surgical rubs) is an *in vivo* test that assesses the efficacy of the test product in reducing the transient flora on volunteers' hands both immediately and after a 3 hour period.
To meet the standard, test products must perform no worse than the reference product n-propanol.

General Study Information	
Protocol:	prEN 12971:2014
Test House:	HygCen GmbH Schwerin, Germany
Date of Report:	3rd March 2015
Report Ref:	SN 17930
Test Product:	Deb® InstantGEL Complete (NW120103a_L)
Study Dates:	21/01/2015 - 20/02/2015

Summary of Test Conditions	
Test Product:	Deb® InstantGEL Complete
Batch Number:	NW120103a_L
Product Test Concentrations:	100% (Neat)
Test Strain:	N/A
Reference Procedure:	3ml aliquots of 60% n-propanol rubbed on the hands, repeated sufficiently to maintain wet hands for 3 minutes
Test Procedure:	3ml aliquots of the test product rubbed on the hands, repeated sufficiently to maintain wet hands for 90 seconds

Test Results:

From the critical values for Wilcoxon`s matched-pairs signed-ranks test the entry for n=25 and a one sided 0.025 level of significance the critical value of 89 is found. Hence c = 89 + 1 = 90. In the body of the table the pair wise differences are sorted in descending order. There the 90th value is 0.06. Hence the Hodges-Lehmann upper one-sided 97.5% confidence limit for the difference in lg RFs between reference product and Deb® InstantGEL Complete is 0.13, which is less than the agreed inferiority margin of 0.75. Therefore, the hypothesis of inferiority of the immediate effect of Deb® InstantGEL Complete versus Reference Product can be rejected and it can be concluded that the test preparation Deb® InstantGEL Complete is non- inferior to Reference Product.

Study Conclusion:

Deb® InstantGEL Complete proved to be suitable for surgical hand rub in a practice-like trial with 25 test persons. The requirements of prEN 12791:2014 (phase 2, step 2) were fulfilled with a use concentration of 100% kept wet for a contact time of 90 seconds.

In vitro Mycobactericidal **EN 14348**

Objective:
Quantitative suspension test for the evaluation of Mycobactericidal activity of chemical disinfectants used in the medical area including instrument disinfectants.

General Study Information	
Protocol:	EN 14348:2005
Test House:	HygCen GmbH Schwerin, Germany
Date of Report:	30th May 2018
Report Ref:	SN 23593
Test Product:	Deb® InstantGEL Complete (NW120103a_L)
Study Dates:	06/03/2018 - 27/03/2018

Summary of Test Conditions	
Test Product:	Deb® InstantGEL Complete
Batch Number:	NW 120103a_L
Product Test Concentrations:	97%, 80% and 50% (v/v) end concentrations
Diluent:	Distilled water
Test Temperature:	20°C ± 1°C
Incubation Temperature:	36°C ± 1°C
Neutraliser:	1.0% polysorbate 80 + 3.0% saponine + 0.1% histidine + 0.5% sodium thiosulphate (NMII)
Conditions:	Clean conditions
Interfering Substance:	0.3g/l bovine albumine
Test Strains:	*Mycobacterium terrae ATCC 15755* *Mycobacterium avium ATCC 15769*
Contact Time:	30 seconds

Test Results:
Mycobacterium terrae and *Mycobacterium avium* were sufficiently (log RF >4) inactivated with the following concentration-time relationship: clean conditions, 80% (v/v), 30 seconds.

Study Conclusion:
Deb® InstantGEL Complete showed mycobactericidal activity under clean conditions and complies with the requirements of EN 14348:2005 (phase 2, step 1) with the following concentration-time relationship: 80% (v/v), 30 seconds.

In vitro Yeasticidal & Fungicidal **EN 1650**

Objective:
Quantitative suspension test for the evaluation of yeasticidal or fungicidal activity of chemical disinfectants in food, industrial, domestic and institutional areas.

General Study Information	
Protocol:	EN 1650:2013
Test House:	Deb R&D Microbiology Dept, Krefeld, DE
Date of Report:	5th February 2015
Report Ref:	2018/155
Test Product:	Deb® InstantGEL Complete
Study Dates:	31/10/14 - 09/12/14

Summary of Test Conditions	
Test Product:	Deb® InstantGEL Complete
Batch Number:	NW120103a_L
Product Test Concentrations:	80%, 50% and 20% (v/v end concentrations)
Diluent:	Distilled Water
Test Temperature:	20°C
Incubation Temperature:	30°C ± 1°C
Neutraliser:	3.0% polysorbate 80, 3.0% saponine, 0.1% histidine, 0.3% lecithine, 0.5% sodium thiosulphate, 0.1% tryptone, 0.9% NaCl
Conditions:	Dirty
Interfering Substance:	3.0 g/l bovine albumin
Test Strains:	*Candida albicans* ATCC 10231
Contact Time:	30 seconds

Test Results:
The test organisms were sufficiently (log RF >4) inactivated with the following concentration-time relationship:

- *Candida albicans*: dirty conditions, 80% (v/v), 30 seconds.

Study Conclusion:
Deb® InstantGEL Complete showed yeasticidal activity under dirty conditions and complies with the requirements of EN 1650:2013 (phase 2, step 1) with the following concentration-time relationship:

- Yeasticidal: dirty conditions, 80% (v/v), 30 seconds

In vitro Yeasticidal & Fungicidal **EN 13624**

Objective:

Quantitative suspension test for the evaluation of yeasticidal or fungicidal activity of chemical disinfectants in the medical area.

General Study Information	
Protocol:	EN 13624:2013
Test House:	HygCen GmbH Schwerin, Germany
Date of Report:	15th March 2018
Report Ref:	SN 23593
Test Product:	Deb® InstantGEL Complete (NW120103a_L)
Study Dates:	02/03/18 – 04/03/18

Summary of Test Conditions	
Test Product:	Deb® InstantGEL Complete (NW120103a_L)
Batch Number:	NW120103a_L
Product Test Concentrations:	80%, 50% and 25% (v/v end concentrations)
Diluent:	Distilled Water
Test Temperature:	20°C
Incubation Temperature:	30°C ± 1°C
Neutraliser:	3.0% polysorbate 80, 3.0% saponine, 0.1% histidine, 0.1% cysteine
Conditions:	Clean
Interfering Substance:	30.3 g/l bovine albumin
Test Strains:	*Candida albicans ATCC 10231*
Contact Time:	30 seconds

Test Results:

The test organisms were sufficiently (log RF >4) inactivated with the following concentration-time relationship:

- *Candida albicans*: clean conditions, 80% (v/v), 30 seconds

Study Conclusion:

According to EN 13624 (phase 2, step 1), Deb® InstantGEL Complete possesses yeasticidal activity >4 log (99.99%) in 30 seconds at 20˚C for the test strain *Candida albicans* when diluted at 80% (v/v) and therefore satisfies the requirements of EN 13624:2013.

In vitro Virucidal **EN 14476 – Poliovirus Type 1**

Objective:

This standard is a quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the medical area. The standard applies to areas and situations where disinfection is medically intended. Such indications occur in patient care; for example in hospitals, community medical facilities, dental institutions, clinics in schools, kindergardens, nursing homes and may occur in the workplace or the home.

General Study Information	
Protocol:	prEN 14476:2011
Test House:	Dr Brill + Dr Steinmann Labs GmbH
Date of Report:	24th February 2012
Report Ref:	E12ML1348Po
Test Product:	Deb® InstantGEL Complete
Study Dates:	19/01/2012 - 24/02/2012

Summary of Test Conditions	
Test Product:	Deb® InstantGEL Complete
Batch Number:	NW120103a_L
Product Test Concentrations:	Undiluted (97% and 80%) and 10% (demonstration of non-active range) v/v solutions
Diluent:	Water
Test Temperature:	20°C ± 1°C
Appearance of product dilutions:	Minor flocculation
Conditions:	Clean conditions
Interfering Substance:	0.3% bovine serum albumin
Procedure to stop action of disinfectant:	Immediate dilution
Stability of product in the mix with virus and interfering substance:	97% and 80% - minor precipitation, no flocculation.
Virus Strains:	*Poliovirus* type 1 strain LSc-2ab (Chiron-Behring)
Contact Time:	30, 60, 120 and 180 seconds

Test Results:

The undiluted product (97% assay) was able to inactivate *poliovirus* type 1 after 60 seconds in the quantitative suspension test. The mean reduction factor was ≥4.03 ± 0.26. The mean value corresponds to an inactivation of >99.99%.

Study Conclusion:

The hand disinfectant Deb® InstantGEL Complete tested undiluted, demonstrated effectiveness against *poliovirus* type 1 after an exposure time of 60 seconds under clean conditions. Therefore, the hand disinfectant Deb® InstantGEL Complete can be declared as active against *poliovirus* type 1 as follows: undiluted, 60 seconds.

In vitro Virucidal **EN 14476 – Adenovirus Type 5**

Objective:

This standard is a quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the medical area. The standard applies to areas and situations where disinfection is medically intended. Such indications occur in patient care; for example in hospitals, community medical facilities, dental institutions, clinics in schools, kindergardens, nursing homes and may occur in the workplace or the home.

General Study Information	
Protocol:	prEN 14476:2011
Test House:	Dr Brill + Dr Steinmann Labs GmbH
Date of Report:	9th March 2012
Report Ref:	B12ML1348A
Test Product:	Deb® InstantGEL Complete
Study Dates:	13/01/2012 - 09/03/2012

Summary of Test Conditions	
Test Product:	Deb® InstantGEL Complete
Batch Number:	NW120103a_L
Product Test Concentrations:	Undiluted (80%) and as 50% and 10% (demonstration of non-active range) v/v solutions
Diluent:	Water
Test Temperature:	20°C ± 1°C
Appearance of product dilutions:	No precipitation
Conditions:	Clean conditions
Interfering substance:	0.3 g/L bovine serum albumin
Procedure to stop action of disinfectant:	Immediate dilution
Stability of product in the mix with virus and interfering substance:	80% - no precipitation, no flocculation
Virus Strains:	*adenovirus* type 5 strain adenoid 75 (ATCC VR-5)
Contact Time:	30, 60 and 120 seconds

Test Results:

The undiluted product (80% assay) was able to inactivate *adenovirus* type 5 after 30 seconds in the quantitative suspension test. The mean reduction factor was ≥4.69 ± 0.37. The mean value corresponds to an inactivation of >99.99%.

Study Conclusion:

The hand disinfectant Deb® InstantGEL Complete tested undiluted demonstrated effectiveness against *adenovirus* type 5 after an exposure time of 30 seconds under clean conditions. Therefore the hand disinfectant Deb® InstantGEL Complete can be declared as active against *adenovirus* type 5 as follows: undiluted, 30 seconds.

In vitro Virucidal **EN 14476 – Murine Norovirus**

Objective:

This standard is a quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the medical area. The standard applies to areas and situations where disinfection is medically intended. Such indications occur in patient care; for example in hospitals, community medical facilities, dental institutions, clinics in schools, kindergardens, nursing homes and may occur in the workplace or the home.

General Study Information	
Protocol:	prEN 14476:2011
Test House:	Dr Brill + Dr Steinmann Labs GmbH
Date of Report:	20th February 2012
Report Ref:	E12ML1348M
Test Product:	Deb® InstantGEL Complete
Study Dates:	19/01/2012 - 20/02/2012

Summary of Test Conditions	
Test Product:	Deb® InstantGEL Complete
Batch Number:	NW120103a_L
Product Test Concentrations:	Undiluted (97% and 80%) and 10% (demonstration of non-active range) v/v solutions
Diluent:	Water
Test Temperature:	20°C ± 1°C
Appearance of product dilutions:	Minor flocculation
Conditions:	Clean conditions
Interfering substance:	0.3 g/L bovine serum albumin
Procedure to stop action of disinfectant:	Immediate dilution
Stability of product in the mix with virus and interfering substance:	80% - no precipitation, no flocculation
Virus Strains:	*murine norovirus* (Berlin 06/06/DE Isolate S99)
Contact Time:	15, 30 and 60 seconds

Test Results:

The undiluted product (80%) was able to inactivate *murine norovirus* after 15 seconds in the quantitative suspension test. The mean reduction factor was ≥4.31 ± 0.17. The mean value corresponds to an inactivation of >99.99%.

Study Conclusion:

The hand disinfectant Deb® InstantGEL Complete tested undiluted demonstrated effectiveness against *murine norovirus* after an exposure time of 15 seconds under clean conditions. Therefore the hand disinfectant Deb® InstantGEL Complete can be declared as active against *murine norovirus* as follows: undiluted, 15 seconds.

In vitro Virucidal **EN 14476 – SARS CoV-2**

Objective:

This standard is a quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the medical area. The standard applies to areas and situations where disinfection is medically intended. Such indications occur in patient care; for example in hospitals, community medical facilities, dental institutions, clinics in schools, kindergartens, nursing homes and may occur in the workplace or the home.

General Study Information	
Protocol:	EN14476:2013+A2:2019
Test House:	Microbac Laboratories Inc
Date of Report:	10th July 2020
Report Ref:	448-107
Test Product:	Instant Gel Complete/Cutan Gel Hand Sanitiser
Study Dates:	09/06/2020 - 08/07/2020

Summary of Test Conditions	
Test Product:	Instant Gel Complete/Cutan Gel Hand Sanitiser
Batch Number:	1494
Product Test Concentrations:	10% (1 part concentrate + 9 parts diluent) 50% (1 part concentration + 1 part diluent) Neat (i.e. ready-to-use)
Diluent:	EN Hard Water
Test Temperature:	20°C ± 1°C
Appearance of product dilutions:	No precipitation
Conditions:	Clean conditions
Interfering substance:	0.3 g/100 mL Bovine Serum Albumin (BSA) (final concentration in reaction mixture 0.3 g/L BSA)
Procedure to stop action of disinfectant:	Immediate dilution
Virus Strains:	*Severe Acute Respiratory Syndrome-related Coronavirus 2 (SARS-CoV-2)* *(COVID-19 Virus), strain: USA-WA1/2020, Source: BEI Resources, NR-52281*
Contact Time:	30 seconds

Study Conclusion:

According to the EN14476:2013+A2:2019 guideline, the test product passes the Virucidal Efficacy Suspension Test if there is at least a 4.0-log reduction in viral titre beyond the cytotoxicity level.

When tested as described, Instant Gel Complete / Cutan Gel Hand Sanitizer, at 10% concentration, did not meet the European Standard EN14476:2013+A2:2019 guideline when Severe Acute Respiratory Syndrome-related Coronavirus was exposed to the test product for 30 seconds at 20°C.

When tested as described, Instant Gel Complete / Cutan Gel Hand Sanitizer, at 50% and Neat concentrations, met the European Standard EN14476:2013+A2:2019 guideline, when Severe Acute Respiratory Syndrome-related Coronavirus was exposed to the test product for 30 seconds at 20°C, with a Log10 reduction of ≥ 4.38 ± 0.18 at each concentration.

All controls met the criteria for a valid test. These conclusions are based on observed data.

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At SC Johnson Professional® we provide expert skin care, cleaning and hygiene solutions for industrial, institutional and healthcare users.

Our product range incorporates the Deb branded range of specialist occupational skin care products along with the well-known SC Johnson brands enhanced for professional use and innovative specialist professional cleaning and hygiene products.

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RETHINKING THE PROFESSIONAL EXPERIENCE