

CERTIFICATE



This is to certify that

Ecolab Deutschland GmbH

Ecolab-Allee 1 40789 Monheim am Rhein Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a Quality Management System.

Scope:

The design and development, manufacture and distribution of products, services and equipment for the Healthcare, Industrial, Institutional and Speciality Water Treatment and Process Chemical Markets.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001: 2008

Certificate registration no.

002201 QM08

Valid from

2017-03-07

Valid until

2018-09-14

Date of certification

2017-03-07

((DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-16074-01-00

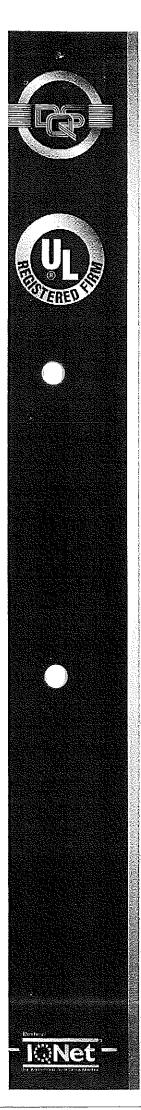
DQS GmbH

Frank Gille

Frank Graichen Managing Director



Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany Administrative Office: DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de



Annex to certificate Registration No. 002201 QM08

Ecolab Deutschland GmbH

Ecolab-Allee 1 40789 Monheim am Rhein Germany

Location

Ecolab Production Belgium BVBA -Equipment Center Essenschot 6031, Industriezone

Essenschot 6031, Industriezone Ravenshout 6 3980 Tessenderlo Belgium

Ecolab Europe GmbH Richtistr. 7 8304 Wallisellen

Switzerland

Ecolab Engineering GmbH Raiffeisenstr, 7 83313 Siegsdorf Germany

Nalco Finland Manufacturing Oy Kivikummuntie 1 07955 Tesjoki Finland

Ecolab Ltd. Lotherton Way, Garforth Leeds LS25 2JY United Kingdom

Ecolab S.A. 25th km., Old National Road Athens Thiva 19600 Mandra Attikis Greece

Ecolab Production Belgium BVBA Havenlaan 4, Ravenshout Bed. 4.210 3980 Tessenderlo Belgium

Nalco Deutschland Manufacturing GmbH und Co. KG Justus-von-Liebig-Str. 11 64584 Biebesheim

Justus-von-Liebig-Str. 1 64584 Biebesheim Germany

Nalco Española Manufacturing SLU Carrer Tramuntana, s/n Poligono Industrial de Ceira, 17460 Ceirá Spain

Ecolab Production France SAS BP 509, Avenue du Général Patton 51006 Chalons-en-Champagne France

NLC Weavergate Winnington Avenue Northwich Cheshire CW84DX United Kingdom

ธับธองสำเนาถูกต้อง

Nalco Budapest Shared Service Center Vaci Ut 81-83, Center Point 2 1139 Budapest Hungary

This annex (edition: 2017-03-07) is only valid in connection with the above-mentioned certificate.



Annex to certificate Registration No. 002201 QM08

Ecolab Deutschland GmbH

Ecolab-Allee 1 40789 Monheim am Rhein Germany

Location

Ecolab Ltd.
Forest Park, Zone C
Mullingar Industrial Estate
Mullingar, Co.
Westmeath
Ireland

Ecolab Production Italy S.r.I. Via Grandi 9/11 20089 Rozzano (MI) Italy

Nalco R&D Leiden Ir. G. Tjälmaweg 1 2342 BV Oegstgeest Netherlands

Nalco Warehouse Den Bosch Europalaan 9 Noord-Brabant 5232 BC Den Bosch Netherlands

Ecolab d.o.o. Vajngerlova 4 2000 Maribor Slovenia

กญะกรานการพิจารณาหลการประกวล

Nalco Nichelino Production Via Vernea 99 10042 Nichelino (Torino) Italy

Nalco Italiana Manufacturing srl Via Ninfina II snc 04012 Cisterna di Latina (LT) Italy

Ecolab Production Netherlands B.V. Brugwal 11 3432 NZ Nieuwegein Netherlands

Ecolab Services Poland Sp. z o.o. Opolska St. 100 31-323 Kraków Poland

อับธองลำเนาถูกต้อง



base First off

D=te:6/2/15

Product Name Product Code

Batch Number

Control specification for the product.



Diversey Europe Operations BV

Maarszenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427

	หละกรรมการสิจารณาผลการประกาล รากาจิเล็กการสมิกส์ 1
Certificate of analysis	5
CLEARKLENS BI-SPORE ACTIVATOR	R SOLUTION VH26
7518162	
FMP15040 37631	
02/2015	
02/2017	

Production Date Expiration Date This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality

Test	Test Method	Lower -	nits Upper	Results
Appearance	Visual		olourless quid	Clar Colouries
pH (100% 20°C)	JDM001	9.0	12.5	11.9
Sp. lific Gravity (20°C)	JDM004	1.004	1.020	1.006
Potential Chlorine Dioxide (ppm)		100	180	145.125ADA

	Name :	China D. Kinonna.
On behalf of Diversey site Quality Manager	Position	Quality Control Inspection อิชล์าเนาถูกต้อง

This document being issued electronically does not bear a signature

COA Bi-Spore Activator Version: 01

Date of issuing : C



Diversey Europe Operations BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 8427

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		วาฐาติปากของลิกส์
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<i></i>		Tuannamanamanamanamanamanamanamanamanaman
Product Name	CLEARKLENS BI-SPORE BA	SE SOLUTION VH26
Product Code	7518162	
Batch Number	FMP15040 376	31.
Production Date	02/2015	
Expiration Date	02/2017	
This is be subjected to the state of		

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	_	mits	Results
Appearance	Visual	Lower - Clear C	<u> </u>	der colourse
		1	ıuid	1,20, d
рН (100% 20°C)	JDM001	1.5	2.5	1.7
ecific Gravity (20°C)	JDM004	1.010	1.030	1.0714

	Name: Clase Okinchina	€.
On behalf of Diversey site Quality Manager Position Quality Control Ins		_

ธับรลงลำเนาถูกต้อง

This document being issued electronically does not bear a signature

COA Bi-Spore Base Version: 01

Date of issuing :



http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 01-Feb-2015

UK32S11320748-1-1

กูญหลดรายภาษาได้ ของกฤษพาร**ท้**วยกรพ

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2006 Sterilisation of Health Care Products

EN ISO 9001:2008 Quality Management System รากในกรรคับไ EN ISO 13485:2012 Quality System - Medical Devices Flexible Medical Packaging Ltd Unit 8, White Cross Ind Estate Hightown A Lancaster 719 mm (2001) (2001) (1000) (2001) (2 Lancashire LA1 4XS UNITED KINGDOM 7..... All in accordance with current Technical Agreement Order Information Account Number: 100432 Synergy Health Sales Part Reference: 1002735 Customer Reference Number: P023691 **Product Description:** JD-BOTTLES/CAPS/BAGS 25-40kGy Validation Reference: Quantity Received: Customer Minimum Specification kGy: 25.0 Customer Maximum Specification kGy: 40.0 Customer Unit Lot/Batch Number: B/N W037630 THUR 29.01,2015 2 PLTS Irradiation Data Date and Time of Irradiation: 01-Feb-2015 18:45 Reference Dose Range kGy: 33,7 - 33,8 Calculated Minimum Dose kGy: 27.9 Calculated Maxlmum Dose kGy: 35.3 ttems Irradiated under WO37630 will be used in finished product batch code FMP15040 37631 $\stackrel{f}{\leftarrow} \stackrel{f}{\leftarrow} e^{i\omega} e^{i\omega} e^{i\omega} = e^{i\omega} e^{i\omega}$

้ **ลั**บธองลำเนาถูกต้อง

Irradiation Release Authorised By Synergy Health plc



Wickham Loborotories Eld Hoeford Point, Barwell Lane, Gosport Hampshire PO13 0AU England

Telephone: Alt. Telephone:

+44(0)1329 226600 +44(0)1329 832511

Fax:

+44[0]1329 832511

mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

Ms D Henderson Flexible Medical Packaging Limited Unit 8 Hightown White Cross Industrial Estate

Date Received:

18 Feb 2015

Date Tested:

05 Mar 2015

Date Test Completed:

19 Mar 2015

ระบรมชอบการพิชารอบกลการประกอด

วากอิเล็กทรอกิกส์

Purchase Order:

23811

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

Test Required;

Lancaster

LA1 4XS

Date Received:

Test Article:

Sample Code:

Batch Ret:

Qiy Received:

0021246/1

Sterility Test by Membrane Filtration (Steritest)

18/02/2015

Bi-Spore Solution (Activator)

491596

FMP 15040 37631

20 x 100mL Bottles

at 30-35°C after 14 days

Volume Tested

MM107/05

MM107/05

MM107/05

MM107/05

Product Standard Data Sheet

MM107/05

FG047/psd

FM04

mments

Additional samples received on 02/03/2015

See NCR PHM 2015 043 and PHM 2015 054

ธับรองสำนนาถูกต้อง

Approval is provided by Electronic Signature. Their name and position is shown below.

MAS

Date: 20 Mar 2015 15:49:55

Mr K.A. Barker

Business Manager - Microbiology

Consignment: 0021246

GLP GMP FDA

Certificate of Analysis - OSMM

Print Number: P0026229

Page 1 of I

Company Registered in England No. 752951 Wickham Laboratories Limited, Registered Office: Hoeford Point, Barwell Lane, Gosport, Hampshire



Wickham Laboratories Ltd Hoeford Point, Barwell Lane, Gosport Hampshire PO13 0AU England

Telephone: All. Telephone: +44(0)1329 226600 +44[0]1329 832511

Fax:

+44(0)1329 832511

mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

Ms D Henderson Flexible Medical Fackaging Limited Unit 8

Date Received:

18 Feb 2015

Hightown

Date Tested:

05 Mar 2015

White Cross Industrial Estate

Date Test Completed:

19 Mar 2015

Lancaster LA1 4XS

Purchase Order:

23811

CERTIFICATE OF ANALYSIS

Láboratory Reference Number:

0021246/2

Test Required:

Sterility Test by Membrane Filtration (Steritest)

18/02/2015

Date Received: Test Article:

Bi-Spore Solution (Base)

Sample Code:

491595

Batch Ref:

FMP 15040 37631

Qfy Received:

20 x 100mL Bottles

MM107/05

FG047/psd

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£11144444	************			211143	 	

าณะกรรมการพิจารณฑผลการประกวด

วบกาลิเก็กพรอชิกส์

			<u> </u>
Test	Method Item	Result	6
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass	7
Growth in Tryptone Soya Broth at 20- 25°C after 14 days	MM107/01	No growth in t	wo broths
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in t	wo broths
Volume Tested	MM107/05	20 x 50 ml	

amments

Product Standard Data Sheet

. .ditional samples received on 02/03/2015

See NCR PHM 2015 043 and PHM 2015 054

รับรองลำเนาถูกต้อง

Approval is provided by Electronic Signature. Their name and position is shown below.

(4.K3***

Date: 20 Mar 2015 15:49:55

20 x 50 mL

FM05

Mr K.A. Barker

Business Manager - Microbiology

Consignment: 0021246

Certificate of Analysis - OSMM

Print Number: P0026229

GLP GMP FDA

Company Registered in England No. 752951 Wickham Laboratories Limited, Registered Office: Hoeford Point, Barwell Lane, Gosport, Hampshire

EM

Prep Solvent-70 Cleaner

กผสกรรมการพิศารณาผลการประกวล
รากาอิเล็กพรคพิกส์
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Technical Bulletin

November, 2001

3M™ Prep Solvent-70 Cleaner: A Stronger Alternative to Isopropyl Alcohol and Water for Many Difficult to Clean Surfaces

Prep Solvent-70 Cleaner is a microencapsulated water-based cleaning solution that can be evaluated as an alternative to the typically suggested isopropyl alcohol and water mix, 50% each, when greater contamination, oil or grime is encountered. Prep Solvent-70 Cleaner has been shown effective when cleaning surfaces contaminated with oil, silicones, and mold release agents.

Benefits

- Higher ultimate adhesion on substrates that contain heavy grime, oil, silicones or mold releases than when using isopropyl alcohol/water solution.
- · Less effort required than when using isopropyl alcohol/water.
- Effective on most bare metals and steel, stainless steel, and painted metals.
- Compatible with 3MTM VHBTM Acrylic Foam Tapes.

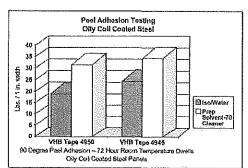
Note: This cleaner contains greater than 250 g/l of volatile organic carbons (VOC).

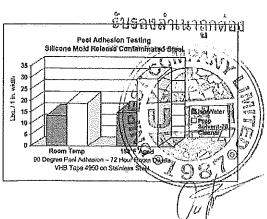
Less water, less exempt solvents. Please contact your local Air Quality

Regulation to be sure the cleaner is compliant.

Testing

Extremely oily metal and silicone contamination can be difficult to clean with isopropyl alcohol/water. The following are test results on stamped metal which underwent a very oily stamping process and panels that were contaminated with silicone release agents.





กณะกรรมการพิจารณาผลการประกวด รากาอิเล็กพรดนิกส์

Technical Bulletin 3M™ Prep Solvent-70 Cleaner

Suggested
Cleaning
Procedures

Apply 3MTM Prep Solvent-70 Cleaner to the surface to be cleaned, either directly or soaking a clean rag or paper towel. Rub vigorously in a scrubbing manner to lift and remove contaminants. Turn rag or paper towel a few times. Rub until most of the Prep Solvent-70 Cleaner has either soaked into the rag or towel and or water has evaporated. Return to give a final "buff" and dry with a new clean paper towel or rag. The surface must be completely dry. The cleaned and dry surface should be ready to accept 3MTM VHBTM tape.

Effectiveness of Prep Solvent-70 Cleaner when cleaning a heavy grimy or oily surface can be verified prior to tape application by giving a second round of cleaning with Prep Solvent-70 Cleaner or another solvent. If properly cleaned, little to no grime or oil will be evident on a new rag or paper towel upon this second application.

Since this solution is 85% water, please keep from freezing. If the solution has been exposed to freezing temperatures, a vigorous shaking is suggested because freezing might induce some separation.

Note: Prep Solvent-70 Cleaner has been evaluated on various materials, but we cannot guarantee it will work on all materials.

Precationary Information

Refer to the Product Label and Material Safety Data Sheet for Health and Safety Information before using this product.

For Additional Information

To request additional product information of to arrange for sales assistance, call toll free 1-800-362-3550 or visit www.3M.com/adhesives. Address correspondence to: 3M Engineered Adhesives Division, 3M Center, Building 220-7E-01, St. Paul, MN 55144-1000. Our fax number is 651-733-9175. In Canada, phone: 1-800-364-3577. In Puerto Rico, phone: 1-787-750-3000. In Mexico, phone: 52-70-04-00.

Important Notice

3M MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining whether the 3M product is fit for a particular purpose and suitable for user's method of application. Please remember that many factors can affect the use and performance of a 3M product in a particular application. The materials to be bonded with the product, the surface preparation of those materials, the product selected for use, the conditions in which the product is used, and the time and environmental conditions in which the product is expected to perform are among the many factors that can affect the use and performance of a 3M product. Given the variety of factors that can affect the use and performance of a 3M product, some of which are uniquely within the user's knowledge and control, it is essential that the user evaluate the 3M product to determine whether it is fit for a particular purpose and suitable for the user's method of application.

Limitation of Remedies and Liability

If the 3M product is proved to be defective, THE EXCLUSIVE REMEDY, AT 3M'S OPTION, SHALL BE TO REFUND THE PURCHASE PRICE OF OR TO REPAIR OR REPLACE THE DEFECTIVE 3M PRODUCT. 3M shall not otherwise be liable for loss or damages, whether direct, indirect, special, incidental, or consequential, regardless of the legal theory asserted, including, but not limited to, contract, negligence, warranty, or strict liability.

This Engineered Adhesives Division product was manufactured under a 3M quality system registered to ISD 9002 standards.

3W

Engineered Adhesives Division 3M Center, Building 220-7E-01 St. Paul, MN 55144-1000



Recycled Paper 40% pre-consumer 10% post-consumer

Printed in U @351 2001

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