

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



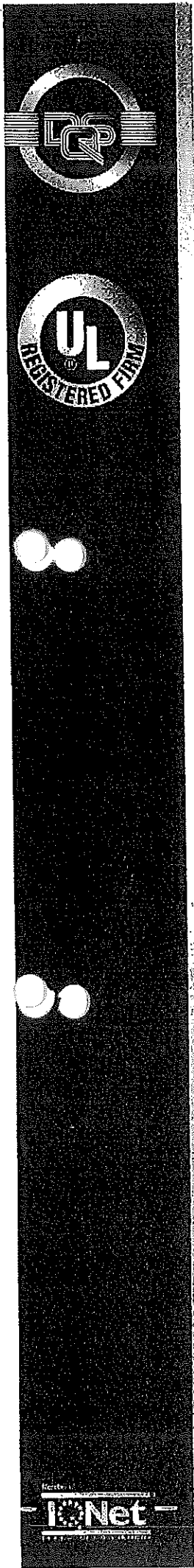
Frank Graichen
Managing Director

DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-15074-01-00



Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Administrative Office: DQS Medizianprodukte 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**
Éssenschot 6031, Industriezone
Ravenshout 6
3980 Tessenderlo
Belgium

Ecolab Europe GmbH
Richtstr. 7
8304 Wallisellen
Switzerland

Ecolab Engineering GmbH
Raiffeisenstr. 7
83313 Siegsdorf
Germany

Nalco Finland Manufacturing Oy
Kivikumuntie: 1
07955 Tesjoki
Finland

Ecolab Ltd.
Lotherton Way, Garforth
Leeds
LS26 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
Germany

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

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

คณะกรรมการการศึกษาคณะกรรมการผู้ทรงคุณวุฒิ
สภาวิชาชีพวิศวกรรมเครื่องกล

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- 2..... *Q.M.*
- 3..... *Q.M.*
- 4.....
- 5.....
- 6.....
- 7.....



**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.l.
Via Grandi 9/11
20089 Rozzano (MI)
Italy

Nalco R&D Leiden
Ir. G. Tjalmaweg 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

Signature of the authorized
personnel

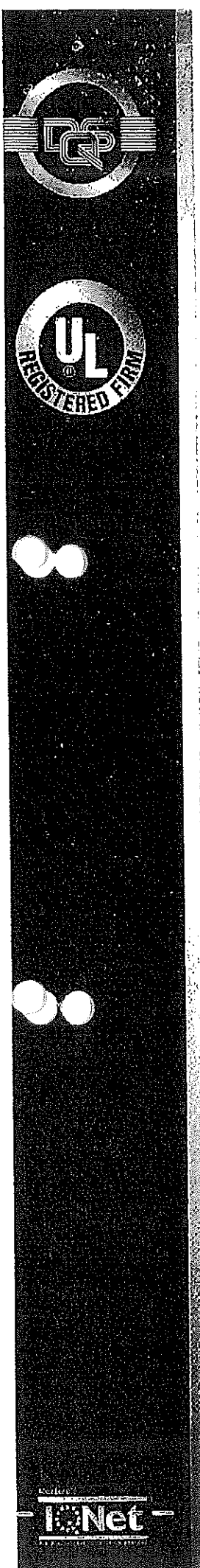
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- 2..... *[Signature]*
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Nalco Nichelino Production
Via Vernea 99
10042 Nichelino (Torino)
Italy

Nalco Italiana Manufacturing srl
Via Ninfina 11 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 Krakow
Poland



base first off



Diversey Europe Operations BV
 Maarssebroeksedijk 2
 3542 DN Utrecht
 The Netherlands
 Tel. +31 (0)30 247 6427

- 1..... *Order*
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CERTIFICATE OF ANALYSIS

Date: 6/2/15

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7513162
Batch Number	FMP150402 37631
Production Date	02/2015
Expiration Date	02/2017

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	Limits		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		Clear Colourless 1.80ml
pH (100% 20°C)	JDM001	9.0	12.5	11.9
Specific Gravity (20°C)	JDM004	1.004	1.020	1.006
Residual Chlorine Dioxide (ppm)		100	180	145.125ppm

On behalf of Diversey site Quality Manager	Name :	<i>[Signature]</i>
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Bi-Spore Activator Version : 01 Date of issuing : October 1 - 2015



RECEIVED 11/21/15
Base first off



Diversey Europe Operations BV
 Maarssebroekedijk 2
 3842 DN Utrecht
 The Netherlands
 Tel. +31 (0)30 247 8427

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CERTIFICATE OF ANALYSIS

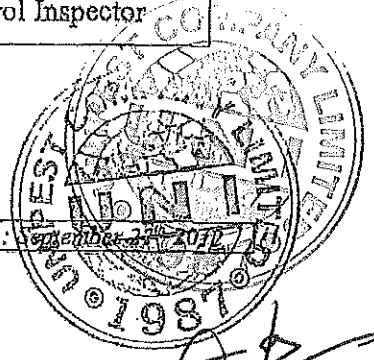
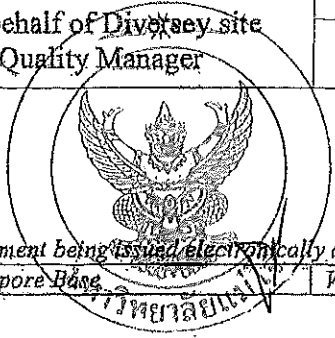
Date: 10/2/15

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7513162
Batch Number	FMP15040 37631
Production Date	02/2015
Expiration Date	02/2017

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	Limits		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		Clear colourless liquid
pH (100% 20°C)	JDM001	1.5	2.5	1.7
Specific Gravity (20°C)	JDM004	1.010	1.030	1.0714

On behalf of Diversey site Quality Manager	Name :	<i>C. O. K. ...</i>
	Position	Quality Control Inspector



This document being issued electronically does not bear a signature.

COA Bi-Spore Base Version : 01 Date of issuing : September 27 2015

[Handwritten signature]



http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 01-Feb-2015

UK32S11320748-1-1

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
- EN ISO 13485:2012 Quality System - Medical Devices

Flexible Medical Packaging Ltd
 Unit 8, White Cross Ind Estate
 Hightown
 Lancaster
 Lancashire LA1 4XS
 UNITED KINGDOM

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All in accordance with current Technical Agreement

Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1002735
Customer Reference Number:	PO23691
Product Description:	JD-BOTTLES/CAPS/BAGS 25-40kGy
Validation Reference:	4.1624
Quantity Received:	8
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 18:46
Reference Dose Range kGy:	33.7 - 33.8
Calculated Minimum Dose kGy:	27.9
Calculated Maximum Dose kGy:	35.3

Items irradiated under W037630 will be used in finished product batch code FMP16040 37631 L. Gough 17 2.15



รับรองสำเนาถูกต้อง



Irradiation Release Authorised By Synergy Health plc

Registered Office: Ground Floor, Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
 Company Registered in England and Wales No: 01771933 VAT Number: GB 813038069



Wickham Laboratories

Contract Analytical Services

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

Ms D Henderson
 Flexible Medical Packaging Limited
 Unit 8
 Hightown
 White Cross Industrial Estate
 Lancaster
 LA1 4XS

Date Received: 18 Feb 2015
 Date Tested: 05 Mar 2015
 Date Test Completed: 19 Mar 2015
 Purchase Order: 23811

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0021246/1
 Test Required: Sterility Test by Membrane Filtration (Steritest)
 Date Received: 18/02/2015
 Test Article: Bi-Spore Solution (Activator)
 Sample Code: 491596
 Batch Ref: FMP 15040 37631
 Qty Received: 20 x 100mL Bottles

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Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soyá Broth at 20-25°C after 14 days	MM107/01	No growth in two broths
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in two broths
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM04

Comments

Additional samples received on 02/03/2015
 see NCR PHM 2015 043 and PHM 2015 054

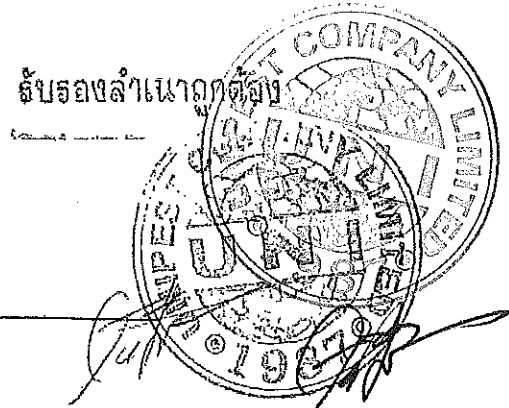


Approval is provided by Electronic Signature and name and position is shown below.

[Signature]

Date: 20 Mar 2015 15:49:55

Mr K.A. Barker
 Business Manager - Microbiology



Consignment: 0021246

Certificate of Analysis - OSMM

Print Number: P0026229

Page 1 of 1

ISO 17025

GLP GMP FDA

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



Wickham Laboratories

Contract Analytical Services

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 Alt. Telephone: +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
 Lancaster
 LA1 4XS

Date Received: 18 Feb 2015
 Date Tested: 05 Mar 2015
 Date Test Completed: 19 Mar 2015
 Purchase Order: 23811

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0021246/2
 Test Required: Sterility Test by Membrane Filtration (Steritest)
 Date Received: 18/02/2015
 Test Article: Bi-Spore Solution (Base)
 Sample Code: 491595
 Batch Ref: FMP 15040 37631
 Qty Received: 20 x 100mL Bottles

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Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in two broths
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in two broths
Volume Tested	MM107/05	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM05

Comments

Additional samples received on 02/03/2015
 See NCR PHM 2015 043 and PHM 2015 054



Approval is provided by electronic signature. Their name and position is shown below.

19/3/15

Date: 20 Mar 2015 15:49:55

Mr K.A. Barker
 Business Manager - Microbiology



Consignment: 0021246

Certificate of Analysis - OSMM

Print Number: P0026229

Page 1 of 1

ISO 17025

GLP GMP FDA

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



Prep Solvent-70 Cleaner

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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.**

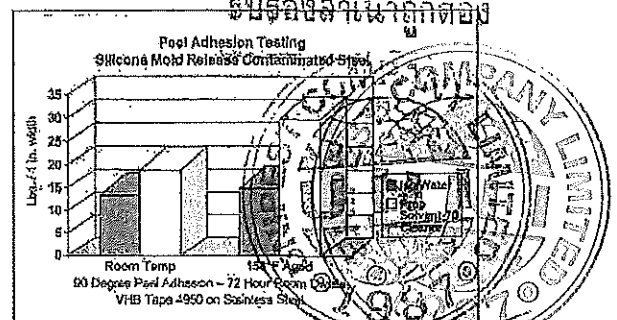
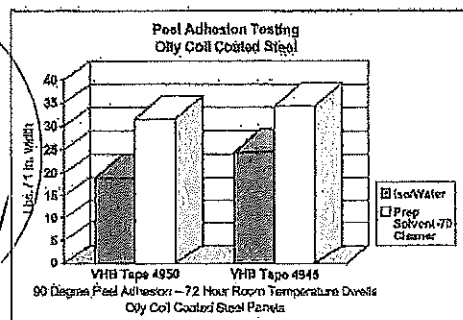
Benefits

- 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 3M™ VHB™ 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.



รับข้อมูลข่าวสารจากที่นี่

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1..... *Phol*

2..... *[Signature]*

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Technical Bulletin

3M™ Prep Solvent-70 Cleaner

Suggested Cleaning Procedures

Apply 3M™ 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 3M™ VHB™ tape.

Effectiveness of Prep Solvent-70 Cleaner when cleaning a heavy grime 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.

Precautionary Information

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

For Additional Information

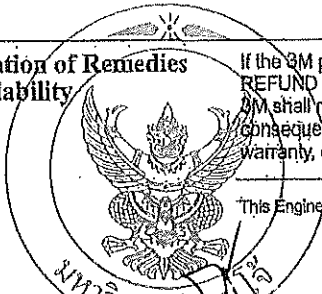
To request additional product information or to arrange for sales assistance, call toll free 1-800-362-3650 or visit www.3M.com/adhesives. Address correspondence to: 3M Engineered Adhesives Division, 3M Center, Building 220-7E-01, St. Paul, MN 55144-1000. Our fax number is 651-733-9175. In Canada, phone: 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.



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



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

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

Printed in U.S.A.
 © 3M 2001 70-0797-2802-3



ได้รับรองว่าเนาถูกต้อง

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