

FIRST OFF



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 8427

CERTIFICATE OF ANALYSIS

Date: 28.09.15

| | |
|-----------------|---|
| Product Name | CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26 |
| Product Code | 100846052 |
| Batch Number | FMP15266, 38808 |
| Production Date | 23/09/2015 |
| Expiration Date | EXP 23/09/2017 |

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 | 9.0 | 12.5 | 11.6 |
| Specific Gravity (20°C) | JDM004 | 1.004 | 1.020 | 1.004 |
| Potential Chlorine Dioxide (ppm) | | 100 | 180 | 157.9ppm |

| | | |
|---|----------|---------------------------|
| On behalf of Diversey site Quality Manager | Name : | H. Hamlen, Parhyishe |
| | 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 st 2012 |
|------------------------|--------------|--|

FIRST OFF



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 28.09.15

| | |
|-----------------|---------------------------------------|
| Product Name | CLEARLENs BI-SPORE BASE SOLUTION VH26 |
| Product Code | 100 846 052 |
| Batch Number | FMP 15266 - 38808 |
| Production Date | 23/09/2015 |
| Expiration Date | EXP 23/09/2017 |

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 | 2.1 |
| Specific Gravity (20°C) | JDM004 | 1.010 | 1.030 | 1.018 |
| | | | | |

| | | |
|---|----------|-----------------------------|
| On behalf of Diversey site Quality Manager | Name : | <i>H. Hinder, Partyislo</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 th 2012 |
|-------------------|--------------|---|



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 07-Sep-2015

UK32S11457583-1-1

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

EN ISO 11137-1:2015 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

All in accordance with current Technical Agreement

Order Information

| | |
|--------------------------------------|---|
| Account Number: | 100432 |
| Synergy Health Sales Part Reference: | 1002735 |
| Customer Reference Number: | P024999 |
| 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: | FMP B/N W038807 THURS 27TH AUG 2015 2 PLTS LOT 3 |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 07-Sep-2015 17:15 |
| Reference Dose Range kGy: | 33.7 - 34.0 |
| Calculated Minimum Dose kGy: | 27.9 |
| Calculated Maximum Dose kGy: | 35.5 |

Items Irradiated under W038807 will be used in finished product number: FMP15266 38808

E. Gwynne 26.10.15

Irradiation Release Authorised By Synergy Health plc

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Fax: +44(0)1329 226688

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: 01 Oct 2015
Date Tested: 10 Oct 2015
Date Test Completed: 24 Oct 2015
Purchase Order: 25207

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0025015/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 01/10/2015
Test Article: Bi-Spore Activator
Sample Code: FMP15266 38808
Batch Ref: 511942
Qty Received: 20 x 100mL Bottles

| 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 | FM04 |

Comments

Test carried out according to current Pharmacopoeias.

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

Date: 26 Oct 2015 12:48:53

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Fax: +44(0)1329 226688

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: 01 Oct 2015
Date Tested: 10 Oct 2015
Date Test Completed: 24 Oct 2015
Purchase Order: 25207

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0025015/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 01/10/2015
Test Article: Bi-Spore Base
Sample Code: FMP15266 38808
Batch Ref: 513475
Qty Received: 20 x 100mL Bottles

| 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

Test carried out according to current Pharmacopoeias.

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

Date: 26 Oct 2015 12:48:53

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology