



Diversey Europe BV  
Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands  
Tel. +31 (0)30 247 6427  
[www.Diversey.com](http://www.Diversey.com)

## Certificate of Analysis

Date 18/08/2021

Article  
SKU 100934589 ClearKlens oxifast 1L sterile

Page 1/1

Batch: SEP/1568315/21/117  
Expiry date: 2023-04  
Manufacturing date: 27/04/2021

| Characteristic<br>Method                             | Unit | Value | lower limit | upper limit | conformity |
|------------------------------------------------------|------|-------|-------------|-------------|------------|
| Peracetic acid<br>MAN LCQ 011                        | %    | 0,09  | 0,07        | 0,10        | Yes        |
| Hydrogen peroxide<br>MAN LCQ 011                     | %    | 3,06  | 2,90        | 3,40        | Yes        |
| Loss TAO 16h at 96°C<br>MAN LCQ 009                  | %    | 0,33  | 0,00        | 2,50        | Yes        |
| Sterility certificate<br>European Pharmacopeia 2.6.1 |      |       |             |             | Yes        |

released on : 18/08/2021

by : LALEVEE

### Comments:

Sterility certificate n° 210722-0150-001

The analysis results above could change over time and in function of the storage temperature. It is imperative to store the products according to the recommended conditions indicated in the MSDS.

\*\*\*End of certificate of analysis\*\*\*



Chalon-sur-Saône, August the 18<sup>th</sup>, 2021

## CERTIFICATE OF STERILITY

BIOXAL SA

Route des Varennes  
BP 30072  
F 71103 CHALON / SAONE  
FRANCE,

Certifies that the product:

CLEARKLENS OXIFAST 1L STERILE  
Item code: 70001369  
Batch number: SEP/1568315/21/117  
Quantity: 1152 bottles,

is sterile, according to sterility test Ph.Eur. 2.6.1.

Samuel LALEVEE

BIOXAL Quality Manager

A handwritten signature in blue ink, appearing to be "S. Lalevee", written over a faint circular stamp.

Labor LS SE &amp; Co. KG Mangelsfeld 4, 5, 6 | 97708 Bad Bocklet | Germany

BIOXAL S.A.  
ZI sud - Secteur A  
Route des Varennes  
71100 CHALON SUR SAÔNE  
FRANKREICH

Fon: +49 (0)97 08/91 00-0  
labor@labor-ls.de  
www.labor-ls.de

Bad Bocklet 11 Aug 2021 / MY / BIOXCh

## Certificate of Analysis

|                    |                                           |                 |             |
|--------------------|-------------------------------------------|-----------------|-------------|
| LS No:             | 210722-0150-001                           | LS Code:        | 1861900 / S |
| Product name:      | CLEARKLENS OXIFAST VH49                   |                 |             |
| Lot No:            | 70001369 client, SEP/1568315/21/117       |                 |             |
| Description:       | CODE CLIENT: BIOXAL, N°COMMANDE: 2102124D |                 |             |
| Entry temperature: | Room Temperature                          |                 |             |
| Your Order No:     | 4500240431 / 21D04966D                    |                 |             |
| Order dated:       | 21 Jul 2021                               | Sample receipt: | 22 Jul 2021 |
| Start of test:     | 27 Jul 2021                               | End of test:    | 11 Aug 2021 |

## Test for Sterility on "ClearKlens Oxifast VH 49, 8 samples à 1 L"

| Parameter                    | Specification / Demands                                                                                                      | Result           |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------|------------------|
| Test Procedure according to: | Ph. Eur. 2.6.1 & USP <71><br>(No product specific suitability test<br>or method transfer for this filling quantity existent) |                  |
| Reference Document:          | Growth Promotion Test (140225-0139-001)                                                                                      |                  |
| Test Method:                 | Membrane Filtration                                                                                                          |                  |
| Test Environment:            | Clean Room                                                                                                                   |                  |
| No. of tested Samples:       | 8 unit(s)                                                                                                                    | 8 unit(s)        |
| Tested Volume per Sample:    | 100 ml                                                                                                                       | 100 ml           |
| Type of Filter Material:     | PVDF (Durapore®)                                                                                                             | PVDF (Durapore®) |
| Test System:                 | TZHLV210 (PVDF)                                                                                                              | TZHLV210 (PVDF)  |
| Nutrient Media:              | TSB & FTM with neutralization agents (C+/T+)                                                                                 | C+/T+            |
| Volume of Used Media:        | 100 ml                                                                                                                       | 100 ml           |
| Start of Incubation:         |                                                                                                                              | 28 Jul 2021      |
| End of Incubation:           |                                                                                                                              | 11 Aug 2021      |
| Period of Incubation:        | At least 14 days                                                                                                             | 14 days          |
| Evaluation:                  | No macroscopic growth visible                                                                                                | complies         |

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.  
This document was created by a GMP-supervised LIMS and approved by electronic signature.

Approved on 11 Aug 2021 at 09:03 by Olivia Halamoda, Specialist Manager.



*Ionisation par rayons gamma (gamma irradiation)*

Etablissement (factory):

IONISOS

Parc Dombes Côtières Activités

01120 Dagneux - France

Tél : +33 (0)4 78 06 41 14

Fax : +33 (0)4 78 06 06 20

[www.ionisos.com](http://www.ionisos.com)

A l'attention de Samuel LALEVEE

BIOXAL

ZI SUD - SECTEUR A -CITE DES VARENNES

71103 Chalon/Saone Cedex

France

### CERTIFICAT DE TRAITEMENT (Treatment certificate)

Nom du client (Treatment done for)

BIOXAL

Référence article client (Product description)

CLEARLENS OXIFAST VH49

Référence BL client (your delivery note)

(N° BL=85070051 du 19/05/2021)

Référence Commande client (your purchase order)

(N° Cde=4500240431 du 08/04/2021)

Numéro de Lot client (your batch)

70001369 SCHULKE ORDER OF STERILITY TEST- LOT  
SEP/1568315/21/117

Quantité de colis (Quantity of boxes)

144

Date de traitement (Treatment date)

15/07/2021

N° de traitement Ionisos (Ionisos treatment number)

21T02469D

N° de commande Ionisos (Ionisos order)

2102124D

### RELEVÉ DES DOSES (Observed doses)

Position

Doses lues (Doses controled) kGy /  
Doses visées (Doses requested) kGy

R

17.0 - 17.6 / 16.2 - 23.2

-

-

-

-

-

-

-

-

-

-

Les doses sont données avec une incertitude de +/- 4.0 % (Dose measurements shown on the treatment certificate are given with an uncertainty of +/- 4.0 %)

Traitement contrôlé par (treatment controlled by) Véronique Castanier

Fait le (date) 20/07/2021