

**CONTROL REPORT**

|   |   |
|---|---|
| <b>Customer</b><br>JOHNSON Diversey LTD | Management Quality Manual n° MMMQ0000 (contractual) |
|---|---|

|   |  |
|---|--|
| <b>Product :</b><br>ClearKlens Cleansinald RTU VH9S | <b>Control report n° :</b><br>CERT 9533B |
| <b>Specification reference :</b><br>NA              | <b>Purchase order n° :</b><br>4700741776 |
| <b>Analyst :</b><br>LGR                             | <b>Date of receipt :</b><br>17/02/2009   |

**CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES**

|   |  |
|---|--|
| <b>Customer's batch n° :</b> ENT 05790 09 048 | <b>ISOTRON certificate n° :</b> 13798601 |
| <b>Date of manufacturing :</b> 17/02/2009     | <b>Produced quantity :</b> 167 x 5L      |
| <b>Expiery date :</b> 17/02/2010              | <b>FIDT N° :</b> FIDT 1812 B             |
| <b>ECP's batch n° :</b> 05790                 | <b>Date of analysis :</b> 17/02/09       |

**Résultats :**

| Analyzed characteristics             | Method of analysis | State in the production | Specification                |
|--------------------------------------|--------------------|-------------------------|------------------------------|
|                                      |                    | Beginning               |                              |
| Appearance (base)<br>20°C            | NA                 | C                       | Clear slightly yellow liquid |
| Specific gravity (base)<br>(20°C)    | IDT0301            | 1,000                   | 0,990 - 1,010                |
| pH (base + activator)<br>(20°C)      | NA                 | 11,7                    | 9,0 - 11,7                   |
| Microbiological contagion of the EDI | IDT0236            | < 1cfu/100mL            | < 10 cfu/100mL               |

C : Conform NC : Not Conform  
NA : Not Applicable

**Conclusion :**  CONFORM  NOT CONFORM

|                 |                             |                                       |
|-----------------|-----------------------------|---------------------------------------|
| Date : 30/06/09 | Edited: L. GRESSE <i>RG</i> | Checked: D. CHEUNG <i>[Signature]</i> |
|-----------------|-----------------------------|---------------------------------------|

**CERTIFICATE OF TREATMENT BY GAMMA RADIATION**

WE UNDERSIGNED :

**Isotron France S.A.S.**

MIN 712  
13323 MARSEILLE CEDEX 14 - FRANCE

**ECP Reçu le**  
08 AVR. 2009  
N° 09040806A

**CERTIFY THAT WE TREATED BY GAMMA RADIATION ACCORDING TO THE SPECIFIC CUSTOMER'S REQUIREMENTS AND TO :**

- the specification of treatment # 224503P
- The requirements of the European Pharmacopoeia
- the results of the dose mapping # 110505 of 30/03/2006

**THE FOLLOWING PRODUCTS : (according to the customer's indication)**

Customer : ECP ENTEGRIS CLEANING PROCESS

Product : 5l BOTTLE KIT

Customer's reference : ORDER # CF 080037 OF 13/01/09

Quantity : 4 PALLETS

Irradiation date : 2009.01.17

Irradiation dose : 18,1 kGy à 25,7 kGy

Irradiation batch number : 13798601

*Clearkems Cleanimald*

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*lot ENT05790 09 048*

*Date fab. 17/02/2009*

*Date per. 17/02/2010*

The control of the applied radiation dose is done by Isotron France SAS using Red Perspex dosimeters calibrated by the English National Physical Laboratory.

**Isotron France S.A.S.,**

**H. OSMAS**  
Process Control Officer

**C. SIMONIN**  
Quality Assistant

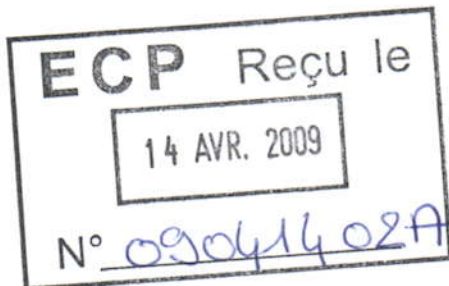
Certificate # 13798601 / 1

English translation of the french original certificate.



# SOCIETE D'ANALYSES INDUSTRIELLES ET SUIVI EN HYGIENE

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ENTEGRIS  
Mr VEYRUNES  
395, Rue LOUIS LEPINE  
34000 MONTPELLIER

Dossier n°090327.45

Metz, le 07.04.09

## **TEST REPORT** **ESSAY OF STERILITY**

*According to the « sterility » protocol described into the fifth European Pharmacopoe Edition  
Addendum 2000*

### **Laboratory which carried out the test**

Laboratory SAIH 26, rue de Neufbourg 57000 METZ, FRANCE

### **Complete identification of the sample**

Name of the product ..... CLEARKLENS CLEANSINALD  
..... (4 plastic packs of 5 liters)  
Number of lot ..... ENT 057 90 09 048 Date of péremption : 17/02/2010  
Manufacturer ..... JOHNSON DIVERSEY  
Storage conditions ..... Original plastic pack, ambient temperature, out of the  
light

### **Method and validation**

Method ..... Filtration on membranes  
Rinsing liquid ..... sterile Trypton salt +0,5% Tween 80  
Membranes ..... Nitrat of cellulose ( porosity 0.45 micron)  
diameter 47 mm. Each unit is sterile  
SARTORIUS N° de lot : 0208114060703823



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## Experiment conditions

Analysis period ..... du 27/03/09 au 07/04/09  
Category ..... 1  
Strains ..... Staphylococcus aureus CIP 4-83  
Bacillus subtilis CIP 52-62  
Pseudomonas aeruginosa CIP 82-48  
Clostridium sporogenes CIP 79-03  
Candida albicans CIP 1180-79  
Aspergillus niger ATCC 16404

## Verification of the method and validation

| Strains                       | Number of viable cells (UFC/ml)              |                   |                    |                      |                       |                     |
|-------------------------------|--|-------------------|--------------------|----------------------|-----------------------|---------------------|
|                               | Bacterial and fungal Suspension of essay (N) | test of growth    |                    |                      | Witness of filtration | Essay of filtration |
|                               |  | N <sub>v</sub>    | Schaedler Solution | Casein Soja Solution | (N <sub>x</sub> )     | (N <sub>y</sub> )   |
| <i>Staphylococcus aureus</i>  | $4,1 \times 10^8$                            | $2,8 \times 10^3$ | +                  | +                    | $2,5 \times 10^3$     | $2,4 \times 10^3$   |
| <i>Bacillus subtilis</i>      | $3,6 \times 10^8$                            | $2,2 \times 10^3$ | +                  | +                    | $2,3 \times 10^3$     | $2,2 \times 10^3$   |
| <i>Pseudomonas aeruginosa</i> | $3,5 \times 10^8$                            | $2,2 \times 10^3$ | +                  | +                    | $2,2 \times 10^3$     | $2,4 \times 10^3$   |
| <i>Clostridium sporogenes</i> | $3,6 \times 10^8$                            | $2,3 \times 10^3$ | +                  | /                    | $2,3 \times 10^3$     | $2,3 \times 10^3$   |
| <i>Candida albicans</i>       | $3,3 \times 10^7$                            | $2,0 \times 10^3$ | /                  | +                    | $1,9 \times 10^3$     | $1,8 \times 10^3$   |
| <i>Aspergillus niger</i>      | $1,5 \times 10^7$                            | $0,6 \times 10^3$ | /                  | +                    | $0,6 \times 10^3$     | $0,5 \times 10^3$   |

For the strains of the test :

N value must be between  $1,5 \times 10^8$ UFC/ml et  $5 \times 10^8$ UFC/ml for bacterial strains ;

N value must be between  $1,5 \times 10^7$ UFC/ml et  $5 \times 10^7$ UFC/ml for fungal strains ;

N<sub>v</sub> value must be between  $6 \times 10^2$ UFC/ml et  $3 \times 10^3$ UFC/ml ;

N<sub>x</sub> value must be over or equal at  $0,5 \times N_v$       N<sub>x</sub>  $\neq$  N<sub>y</sub>

N<sub>y</sub> value must be over or equal at  $0,5 \times N_v$

The method is valid for the strains



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## Sterility control of the environmental growth solutions

| Environmental growth solutions | incubation of temperature $\pm 1^{\circ}\text{C}$ | After 14 days of incubation           |
|--------------------------------|---|---------------------------------------|
| Schaedler Solution             | 31°C  | None bacterial or fugal developpement |
| Casein Soja Casein             | 31°C  | None bacterial or fugal developpement |
| Soja Solution                  | 24°C  | None bacterial or fugal developpement |

## Results of essay

| After 14 days of incubation | Total aerobic flore at 31°C $\pm 1^{\circ}\text{C}$ | Total anaérobic flore at 31°C $\pm 1^{\circ}\text{C}$ | Fungal flore at 24°C $\pm 1^{\circ}\text{C}$ |
|-----------------------------|---|---|--|
| Essai 1                     | 0   | 0   | 0  |
| Essai 2                     | 0   | 0   | 0  |
| Essai 3                     | 0   | 0   | 0  |

## Conclusion

According to the fifth European Pharmacopee Edition Addendum 2000, the product CLEARKLENS IPA 70% (4 plastic flasks of 5 liters) ENT 057 90 09 048 Date of peremption : 17/02 /2010 doesn't shown any microbial development after 14 days of incubation into recommanded conditions.

Metz, 07/04/2009

The Biologist  
Corinne GUITTON-BAERMANN



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## Packaging

|                          |    |
|--------------------------|----|
| Paperboard packages..... | OK |
| Closing mechanism .....  | OK |
| Plastic packs.....       | OK |