



CONTROL REPORT

Customer JOHNSON Diversey LTD		Management Quality Manual n° MMMQ0000 (contractual)	
Product : ClearKlens Cleansinald RTU VH9S		Control report n° : CERT 9511	
Specification reference : NA		Purchase order n° : 4700729880	
Analyst : LGR		Date of receipt : 06/02/2009	

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

Customer's batch n° : ENT 05636 09 037

ISOTRON certificate n° : 13752101

Date of manufacturing : 06/02/2009

Produced quantity : 480 x 5L

Expiry date : 06/02/2010

FIDT N° : FIDT 1812 A

ECP's batch n° : 05636

Date of analysis : 06/02/09

Résultats :

Analyzed characteristics	Method of analysis	State in the production				Specification
		Beginning	middle 1	middle 2	end	
Appearance 20°C	NA	C	C	C	C	Clear slightly yellow liquid
Specific gravity (base) (20°C)	IDT0301	1,000	1,000	1,000	1,000	0,990 - 1,010
pH (base) (20°C)	NA	10,4	10,4	10,4	10,4	9,0 - 10,5
Microbiological contagion of the EDI	IDT0236	< 1cfu/100mL	NA			< 10 cfu/100mL

C : Conform NC : Not Conform
NA : Not Applicable

Conclusion :

☒

CONFORM

☐

NOT CONFORM

Date : 06/02/09

Edited: L. GRESSE

Checked: F. GAYRAUD

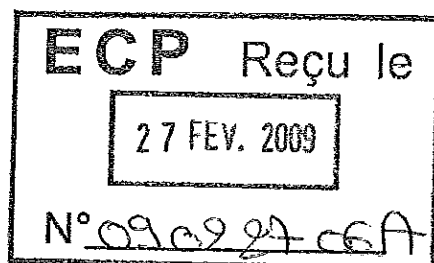
Approved: E. GARY



SOCIETE D'ANALYSES INDUSTRIELLES ET SUIVI EN HYGIENE

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ENTEGRIS
Mr VEYRUNES
395, Rue LOUIS LEPINE
34000 MONTPELLIER



Dossier n°090212.23

Metz, le 26.02.09

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
..... (10 plastic packs of 5 liters)
Number of lot ENT 056 36 09 037 Date of péremption : 06/02/2010
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 12/02/09 au 26/02/09
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 (Nx)	Essay of filtration (Ny)
		Nv	Schaedler Solution	Casein Soja Solution		
<i>Staphylococcus aureus</i>	3,5 x 10 ⁸	2,0 x 10 ³	+	+	1,9 x 10 ³	2,0 x 10 ³
<i>Bacillus subtilis</i>	3,3 x 10 ⁸	2,0 x 10 ³	+	+	1,7 x 10 ³	1,7 x 10 ³
<i>Pseudomonas aeruginosa</i>	3,9 x 10 ⁸	2,3 x 10 ³	+	+	2,2 x 10 ³	2,0 x 10 ³
<i>Clostridium sporogenes</i>	3,9 x 10 ⁸	2,2 x 10 ³	+	/	2,2 x 10 ³	2,2 x 10 ³
<i>Candida albicans</i>	3,9 x 10 ⁷	2,3 x10 ³	/	+	2,2 x 10 ³	2,1 x 10 ³
<i>Aspergillus niger</i>	1,5 x 10 ⁷	0,6 x 10 ³	/	+	0,5 x 10 ³	0,5 x 10 ³

For the strains of the test :

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

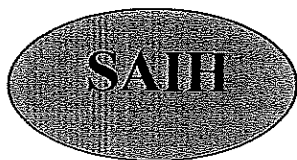
N value must be between $1,5 \times 10^7$ UFC/ml et 5×10^7 UFC/ml for fungal strains ;

N_v value must be between 6×10^2 UFC/ml et 3×10^3 UFC/ml ;

N_x value must be over or equal at $0,5 \times N_v$ N_x $\approx$ N_y

N_y 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 fungal developpement
Casein Soja Casein Soja Solution	31°C	None bacterial or fungal developpement
	24°C	None bacterial or fungal developpement

Results of essay

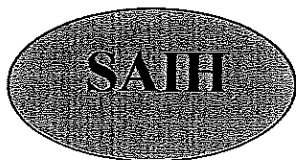
After 14 days of incubation	Total aerobic flore at 31°C $\pm 1^{\circ}\text{C}$	Total anaérobic flore at 31°C $\pm 1^{\circ}\text{C}$	Fungal flore at 24°C $\pm 1^{\circ}\text{C}$
Essai 1	0	0	0
Essai 2	0	0	0
Essai 3	0	0	0

Conclusion

According to the fifth Europeen Pharmacopee Edition Addendum 2000, the product CLEARKLENS CLEANSINALD (10 plastic flasks of 5 liters) ENT 056 36 09 37 Date of peremption : 06/02/2010 doesn't shown any microbial development after 14 days of incubation into recommended conditions.

Metz, 26/02/2009

The Biologist
Corinne GUITTON-BAERMANN



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Dossier n° 090212.23

Metz, le 26/02/2009

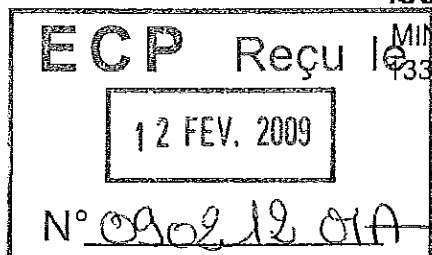
Packaging

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

CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

Isotron France S.A.S.



MIN 712

9323 MARSEILLE CEDEX 14 - FRANCE

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 dosmapping # 110505 of 30/03/2006

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

Customer : ECP ENTEGRIS CLEANING PROCESS

Product : BOTTLES 5L KITS

Customer's reference : ORDER # CF 080037 OF 23/12/08

Quantity : 4 PALLETS

Irradiation date : 2008.12.26

Irradiation dose : 17.9 kGy to 26.7 kGy

Irradiation batch number : 13766201

Checkers Cleanimad RTU

Lot ENT05636 09 37

Date job. 06/02/09

Date per. 06/02/10

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

Certificate # 13766201 / 1

English translation of the french original certificate

C. SIMONIN

Quality Assistant

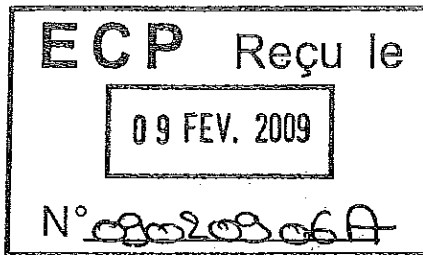
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- the results of the dose mapping # 110505 of 30/03/2006

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

Customer : ECP ENTEGRIS CLEANING PROCESS

Product : BOTTLES KITS 5L & 1L

Customer's reference : ORDER # CF 080037 OF 18/12/08

Quantity : 3 PALLETS

Irradiation date : 2008.12.20

Irradiation dose : 17.6 kGy to 26.8 kGy

Irradiation batch number : 13752101

Cherakemo Cherakemo
Lot ENT05636 09 037
Date fab 06/02/09
Date per 06/02/10

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

A handwritten signature in black ink.

Certificate # 13752101 / 2

C. SIMONIN

Quality Assistant

A handwritten signature in black ink.