

CONTROL REPORT

Customer JOHNSON Diversey LTD		Management Quality Manual n° MMMQ0000 (contractual)	
Product : Clearklens Bi-Spore RTU VH26S		Control report n° : CERT 9331	
Specification reference :		Purchase order n° : 4700713568	
Analyst : LGR		Date of receipt : 04/11/2008	

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

Customer's batch n° : ENT04504	ISOTRON certificate n° : 13404301
Date of manufacturing : 04/11/2008	Produced quantity : 411 x 5L x 100mL
Expiery date : 04/11/2009	FIDT N° : FIDT 1816 0
ECP's batch n° : 04504	Date of analysis : 04/11/08

Résultats :

Analyzed characteristics	Method of analysis	State in the production	Specification
		Beginning	
Appearance 20°C Base solution	NA	C	Clear blue liquid
Appearance 20°C Combined Activator/Base solution	NA	C	Yellow liquid
Dosage of the content it chlorine dioxide	IDT à définir	NA	230-280ppm
Specific gravity (20°C) Base solution	IDT0301	0,998	0,990 - 1,010
Specific gravity (20°C) Combined Activator/Base solution	IDT0301	1,000	1,000 - 1,010
pH (20°C) Base solution	IDT à définir	2,6	2,5 - 4,5
pH (20°C) Combined Activator/Base solution	IDT à définir	2,7	2,5 - 5,5
Microbiological contagion of the EDI	IDT0236	< 1 CFU /100mL	< 10 cfu/100mL

C : Conform NC : Not Conform

NA : Not Applicable

Conclusion : ☒ CONFORM ☐ NOT CONFORM

Date : 04/11/08	Edited : L. GRESSE	Checked : F. GAYRAUD	Approved : C. GARY
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CONTROL REPORT

Customer JOHNSON Diversey LTD		Management Quality Manual n° MMMQ0000 (contractual)	
Product : Clearklens Bi-Spore RTU VH26S		Control report n° : CERT 9428	
Specification reference : NA		Purchase order n° : 4700741776	
Analyst : LGR		Date of receipt : 04/11/2008	

CONTRÔLE DES PROPRIETES PHYSIQUES ET CHIMIQUES

Customer's batch n° : ENT04504 08 309 et ENT05108 08 357	ISOTRON certificate n° : 13409601
Date of manufacturing : 04/11 et 22/12/2008	Produced quantity : 167 x 5L x 100mL
Expiery date : 04/11/2009	FIDT N° : FIDT 1816 0
ECP's batch n° : 04504 et 05108	Date of analysis : 22/12/08

Résultats :

Analyzed characteristics	Method of analysis	State in the production	Specification
		Beginning	
Appearance 20°C Base solution	NA	C	Clear blue liquid
Appearance 20°C Combined Activator/Base solution	NA	C	Yellow liquid
Dosage of the content it chlorine dioxide	IDT à définir	230ppm	230-280ppm
Specific gravity (20°C) Base solution	IDT0301	0,999	0,990 - 1,010
Specific gravity (20°C) Combined Activator/Base solution	IDT0301	1,000	1,000 - 1,010
pH (20°C) Base solution	IDT à définir	2,6	2,5 - 4,5
pH (20°C) Combined Activator/Base solution	IDT à définir	2,7	2,5 - 5,5
Microbiological contagion of the EDI	IDT0236	< 1 CFU /100mL	< 10 cfu/100mL

C : Conform NC : Not Conform

NA : Not Applicable

Conclusion :☒ CONFORM☐ NOT CONFORM

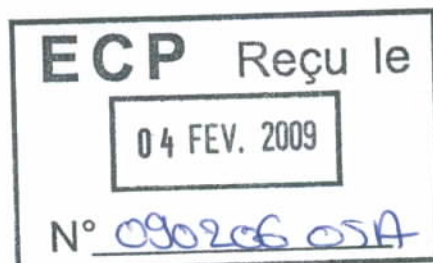
Date : 22/12/08	Edited: L. GRESSE	Checked: F. GAYRAUD	Approved: C. GARY
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SOCIETE D'ANALYSES INDUSTRIELLES ET SUIVI EN HYGIENE

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ENTEGRIS
Mr VEYRUNES
395, Rue LOUIS LEPINE
34000 MONTPELLIER



Dossier n°081231.41

Metz, le 14.01.09

TEST REPORT **ESSAY OF STERILITY**

*According to the « sterility » protocol described into the fifth European Pharmacopée 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 BI-SPORE
(3 plastic packs of 4.9 liters +3 small plastic packs of 0.1 liters)
Protocol : pour the liquid of the small pack into the big one ; mix during 2 min ; waiting
during 10 min then the essay of sterility is beginning)
Number of lot (pack of 4.9l) ... ENT 051 08 08 357 preemption date: 04/11/2009
Number of (pack of 0.1l) ENT 045 04 08 309 péremption date : 04/11/2009
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 31/12/08 au 14/01/09
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>	4,2 x 10 ⁸	2,5 x 10 ³	+	+	2,4 x 10 ³	2,4 x 10 ³
<i>Bacillus subtilis</i>	3,3 x 10 ⁸	1,8 x 10 ³	+	+	2,0 x 10 ³	1,9 x 10 ³
<i>Pseudomonas aeruginosa</i>	2,8 x 10 ⁸	1,9 x 10 ³	+	+	1,8 x 10 ³	1,6 x 10 ³
<i>Clostridium sporogenes</i>	3,5 x 10 ⁸	2,0 x 10 ³	+	/	2,1 x 10 ³	2,2 x 10 ³
<i>Candida albicans</i>	3,5 x 10 ⁷	2,0 x10 ³	/	+	1,9 x 10 ³	1,8 x 10 ³
<i>Aspergillus niger</i>	1,6 x 10 ⁷	0,6 x 10 ³	/	+	0,7 x 10 ³	0,6 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 $\neq$ 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 fugal developpement
Casein Soja Casein Soja Solution	31°C	None bacterial or fugal developpement
	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 Pharmacopée Edition Addendum 2000, the product CLEARKLENS BI-SPORE (3 plastic packs of 4.9 liters +3 small plastic packs of 0.1 liters)
Number of lot (pack of 4.9l)..... ENT 051 08 08 357 preemption date: 04/11/2009
Number of (pack of 0.1l)..... ENT 045 04 08 309 péremption date : 04/11/2009
doesn't shown any microbial development after 14 days of incubation into recommended conditions.

Metz, 14/01/2009

**The Biologist
Corinne GUITTON-BAERMANN**



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Dossier n° 081231.41

Metz, le 14/01/2009

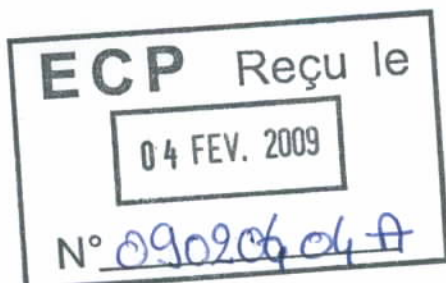
Packaging

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



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34000 MONTPELLIER

Dossier n°081127.49

Metz, le 11.12.08

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 BI-SPORE ACTIVATOR RTU VH26S
(3 plastic packs of 5 liters +3 small plastic packs to mix)
Protocol : pour the liquid of the small pack into the big one ; mix during 2 min ; waiting
during 10 min then the essay of sterility is beginning)
Number of lot ENT 045 04 08 309 preemption date: 04/11/2009
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 27/11/08 au 11/12/08
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>	$3,6 \times 10^8$	$2,2 \times 10^3$	+	+	$2,2 \times 10^3$	$2,2 \times 10^3$
<i>Bacillus subtilis</i>	$3,4 \times 10^8$	$2,0 \times 10^3$	+	+	$2,0 \times 10^3$	$2,1 \times 10^3$
<i>Pseudomonas aeruginosa</i>	$3,0 \times 10^8$	$2,0 \times 10^3$	+	+	$1,9 \times 10^3$	$2,1 \times 10^3$
<i>Clostridium sporogenes</i>	$3,8 \times 10^8$	$2,3 \times 10^3$	+	/	$2,3 \times 10^3$	$2,3 \times 10^3$
<i>Candida albicans</i>	$4,2 \times 10^7$	$2,5 \times 10^3$	/	+	$2,5 \times 10^3$	$2,6 \times 10^3$
<i>Aspergillus niger</i>	$1,5 \times 10^7$	$0,5 \times 10^3$	/	+	$0,6 \times 10^3$	$0,6 \times 10^3$

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 $\neq$ 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 BI-SPORE ACTIVATOR RTU VH26S (3 plastic packs of 5 liters +3 small plastic packs to mix) Number of lot ENT 045 04 08 309 preemption date: 04/11/2009 doesn't shown any microbial development after 14 days of incubation into recommended conditions.

Metz, 11/12/2008

**The Biologist
Corinne GUITTON-BAERMANN**



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ENTEGRIS
Mr VEYRUNES
395 Rue Louis Lépine
34000 MONTPELLIER

Dossier n° 081127.49

Metz, le 11.12.2008

Packaging

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

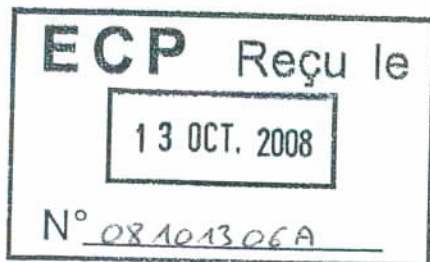
CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

Isotron France S.A.S.

MIN 712

13323 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 dose mapping # 110505 of 30/03/2006

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

Customer : ECP ENTEGRIS CLEANING PROCESS

Product : KITS BIDONS 5l

Customer's reference : Order # CF 080037 of 26/08/08

Quantity : 4 pallets

Irradiation date : 2008.08.27

Irradiation dose : 21.1 kGy to 27.4 kGy

Irradiation batch number : 13404301

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.,

S. LE GONIDEC

Production Assistant

Certificate # 13404301 / 2

C. SIMONIN

Quality Assistant

CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

Isotron France S.A.S.

MIN 712

13323 MARSEILLE CEDEX 14 - FRANCE

ECP Reçu le
04 NOV. 2008
N° <u>08110503A</u>

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

- the specification of treatment # ESSAI 1 DOSE
- the requirements of European Pharmacopea

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

Customer : ECP ENTEGRIS CLEANING PROCESS

Product : BOTTLE 100ML & STOPPER

Customer's reference : ORDER # CF080627 OF 23/10/08

Quantity : 1 PALLET

Irradiation date : 2008.10.28

Irradiation dose : 28.5 kGy to 35.0 kGy

Irradiation batch number : 13590101

EESC Contrôle Réception	
date :	03/11/08
nom :	
visa :	
n° cde	080627
CONFORME	
NON CONFORME	
FA n°	

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

JF 08/02/

Isotron France S.A.S,

H. OSMAS

Process Control Officer



Certificate # 13590101/1

C. SIMONIN

Quality Assistant



CERTIFICATE OF TREATMENT BY GAMMA RADIATION

WE UNDERSIGNED :

Isotron France S.A.S.

MIN 712
13323 MARSEILLE CEDEX 14 - FRANCE

ECP Reçu le

13 OCT. 2008

N° 08101305A

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 dosimetry # 110505 of 30/03/2006

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

Customer : ECP ENTEGRIS CLEANING PROCESS

Product : Kits bidons 5l

Customer's reference : Order # CF 080037 of 28/08/08

Quantity : 3 pallets

ClearKlenz Bi-Spore RTU VH265

*Batches = ENT04504 08 309 and
ENT 05108 08 357*

Irradiation date : 2008.08.29

*Date of manufacturing = 04/11/08 and
22/12/08*

Irradiation dose : 17.1 kGy to 23.6 kGy

Irradiation batch number : 13409601

Expiry date = 04/11/2009

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

F. COURTOIS
02/03/09

F. Courtois

Isotron France S.A.S.,

S. LE GONIDEC

Production Assistant

Certificate # 13409601 / 2

C. SIMONIN

Quality Assistant

ENTEGRIS CLEANING PROCESS

E C P

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info@ecp-entegris.com
www.ecp-entegris.com
443 186 560 RCS Montpellier TVA FR 55 443 186 560

CERTIFICAT DE TRAITEMENT PAR RAYONNEMENT GAMMA

NOUS SOUSSIGNES :

Isotron France S.A.S.

MIN 712

13323 MARSEILLE CEDEX 14 - FRANCE

ECP Reçu le

04 SEP. 2008

N° 08090403A

CERTIFIONS AVOIR TRAITE PAR RAYONNEMENT GAMMA CONFORMEMENT AUX SPECIFICATIONS PARTICULIERES DU CLIENT ET SELON :

- la spécification de traitement n° 224503P
- les prescriptions de la Pharmacopée Européenne
- les résultats de la cartographie n° 110505 du 30/03/2006

LES PRODUITS SUIVANTS : (selon les indications du client)

Client	:	ECP ENTEGRIS CLEANING PROCESS
Produit	:	KITS BIDONS 5l
Référence client	:	CDE N° CF 080037 DU 26/08/08
Quantité	:	4 PALETTES
Date d'irradiation	:	27/08/2008
Dose d'irradiation	:	21,1 kGy à 27,4 kGy
N° de lot de traitement	:	13404301

Le contrôle de la dose d'irradiation a été effectué par Isotron France SAS avec des dosimètres de type Red Perspex calibrés par le Laboratoire National de Physique du Royaume Uni.

Isotron France S.A.S.,

H. OSMAS

Responsable Contrôle Procédé



Certificat n° 13404301 / 1

C. SIMONIN

Assistante Qualité

