DOSSIER SCIENTIFIQUE
SCIENTIFIC REPORT

PHAGO'SURF 2D

Détergent désinfectant pour l'hygiène des sols, des surfaces et du matériel en environnement à risques – Produit biocide (TP2, TP4)

Disinfectant detergent for the hygiene of floors, surfaces and equipment in high-risk environments – Biocidal product (PT2, PT4)

- ✓ Large spectre d'activité
  Broad spectrum of activity
- ✓ Séchage rapide sans traces
  Fast drying without traces
- ✓ Sans parfum
  Fragrance free
- ✓ Produit "contact alimentaire" (conformément à l'arrêté du 8 septembre 1999 et ses modifications)
  "Food contact" product (in accordance with the decree of September 8, 1999 and its modifications)

Christeyns France S.A. 31 rue de la Maladrie 44120 VERTOU
T +33 2 40 80 27 27 **E** info@christeyns.com **E** www.christeyns.com
RCS NANTES B 321 302 689 00013 | APE 2041Z

Sommaire / *Table content*

1. Introduction / *Introduction*

Le **PHAGO'SURF 2D** est un liquide concentré destiné au nettoyage et à la désinfection des sols, surfaces et matériels en environnement à risques. C'est un nettoyant efficace et un désinfectant à large spectre (bactéricide, tuberculocide, fongicide et actif sur virus).

Le **PHAGO'SURF 2D** peut être utilisé, avec un rinçage à l'eau, sur les surfaces susceptibles d'entrer en contact direct avec les denrées alimentaires (conformément à l'arrêté du 8 septembre 1999 et ses modifications).

Le **PHAGO'SURF 2D** est un biocide TP02, TP04.

Ayant la double propriété de détergence et de désinfection, le **PHAGO'SURF 2D** assure le nettoyage et la désinfection rapides des surfaces en une seule opération permettant ainsi un gain de temps et une simplification du travail.

PHAGO'SURF 2D is a concentrated liquid intended for cleaning and disinfection of floors, surfaces and equipment in high-risk environments. It is an effective cleaner and broad-spectrum disinfectant (bactericide, tuberculocide, fungicide and active on virus).

PHAGO'SURF 2D can be used, with water rinsing, on surfaces likely to come into direct contact with foodstuffs (in accordance with the decree of September 8, 1999 and its modifications).

PHAGO'SURF 2D is a TP02, TP04 biocide.

*Having the dual property of detergency and disinfection, **PHAGO'SURF 2D** ensures the cleaning and disinfection of surfaces in a single operation thus saving time and simplifying work.*

2. Composition / *Composition*

Substances actives antimicrobiennes (% m/m) /*Antimicrobial actives substances (w/w %)*

- Chlorure de didécyldiméthylammonium (CAS N° 7173-51-5) : 3,50 %
  Didecyldimethylammonium chloride
- Alkylamine (CAS N° 2372-82-9) : 5,50 %
  Alkylamine

Autres ingrédients / *Other ingredients*

- Agents de surface non ioniques <5%
  Nonionic surfactants <5%

3. Caractéristiques physico-chimiques / *Physico-chemical characteristics*

- Aspect : liquide limpide
  Appearance: Clear liquid
- Couleur : incolore à jaune
  Colour: colorless to yellow-orange
- pH à 20°C (produit pur) : 9,1 ± 0,3
  pH at 20 ° C (pure product): 9.1 ± 0.3
- pH à 20°C (produit dilué à 0,25%, eau du réseau) : environ 8,0
  pH at 20 ° C (Diluted product at 0,25%, tap water): approximately 8.0
- Densité à 20°C : 1,054 ± 0,005
  Density at 20 ° C: 1.054 ± 0.005

4. Mode d'emploi et conditions d'utilisation / *Instructions for use*

Usage réservé aux utilisateurs professionnels.
Procéder tout d'abord à un balayage ou à essuyage humide pour enlever les grosses poussières.
En milieu alimentaire, effectuer un prélavage pour retirer les souillures visibles.
Porter les EPI adaptés selon les recommandations de la Fiche de Données de Sécurité.
Diluer une dose de 20ml de **PHAGO'SURF 2D** dans 8 litres d'eau froide ou tiède du réseau (soit une dilution à 0,25%).

Mode d'emploi selon le conditionnement utilisé :

- Dose de 20ml :

Déchirer la dose au niveau de l'encoche et vider le contenu dans le seau de nettoyage.

- Flacon 1L doseur :

A la première utilisation, retourner le flacon en gardant le capuchon fermé pour charger la première dose dans le bouchon doseur, cette opération n'est nécessaire que lors de la première utilisation.
Pour doser le produit, ouvrir le capuchon retourner le flacon en le tenant bien à la verticale, la dose de 20 ml est distribuée.
Retourner le flacon dans sa position initiale pour recharger la dose qui servira au prochain dosage et ainsi de suite jusqu'à la fin du flacon.

- Bidon de 5L :

Mettre en place une pompe délivrant un volume de 20ml sur le bidon.
Amorcer la pompe, puis appuyer sur la tête au-dessus du bac pour y déverser son contenu.
Le bidon peut également être raccordé à une centrale de dilution automatique.

NB : en cas de fortes salissures, faire un premier passage avec un détergent neutre avant le Phago'surf 2D ou changer la solution Phago'surf 2D et renouveler l'opération.

Protocoles :

✓ Sols :

- **Méthode des 2 seaux**

Préparer un seau d'eau et un seau contenant le produit dilué.
Immerger les franges (MOPS) dans le seau pour les imprégner en respectant les recommandations du fabricant.
Utiliser la méthode de nettoyage de sol définie par le protocole en place. Nous contacter si besoin d'un protocole adapté.
Les seaux ne doivent servir qu'à une seule pièce. Renouveler la solution autant de fois que nécessaire.
Toute autre méthode du type balayage ou essuyage humide permettant d'éliminer préalablement les taches et les saletés peut être retenue.
Ne pas rincer *

✓ Autres surfaces :

- Murs : balayage humide, ne pas rincer *
- Mobiliers, sanitaires : essuyage humide, ne pas rincer *
- Matériel de nettoyage : rinçage, essuyage humide, ne pas rincer *
- Siphons : verser une dose, laisser en contact 15 minutes avant de faire couler de l'eau

* D*ans le cas de désinfection de surfaces susceptibles d'entrer en contact direct avec les denrées alimentaires, un rinçage à l'eau potable est nécessaire (conformément à l'arrêté du 8 septembre 1999 et ses modifications).*

Professional use only.

Sweep or wet wipe off first to remove coarse dust.
In a food environment, perform a pre-wash to remove visible soiling.
Wear the appropriate PPE according to the recommendations of the Safety Data Sheet.
*Dilute a 20ml dose of **PHAGO'SURF 2D** in 8 liters of cold or lukewarm tap water (i.e. a 0.25% dilution).*

Instructions for use according to the packaging used:

- Dose of 20ml:

Tear off the dose at the notch and empty the contents into the cleaning bucket.

- 1L measuring bottle:

On first use, turn the bottle over, keeping the cap closed to load the first dose into the measuring cap, this operation is only necessary for the first use.
To dose the product, open the cap, turn the bottle upside down, holding it upright, the 20 ml dose is dispensed.
Return the vial to its original position to reload the dose for the next dose and so on until the end of the vial.

- 5L can:

Set up a pump delivering a volume of 20ml on the can.
Prime the pump, then press the head above the container to pour out its contents.
The container can also be connected to an automatic dilution unit.

NB: in the event of heavy soiling, make a first pass with a neutral detergent before Phago'surf 2D or change the Phago'surf 2D solution and repeat the operation.

Protocols:

✓ *Floors*:

• *2 buckets method*

Prepare a bucket of water and a bucket containing the diluted product.
Immerse the mops (MOPS) in the bucket to soak them according to the manufacturer's recommendations.
Use the floor cleaning method defined by the protocol in place. Contact us if you need a suitable protocol.
Buckets should only be used for one room. Renew the solution as many times as necessary.
Any other method such as sweeping or wet wiping to remove stains and dirt beforehand can be used.
*Do not rinse **

✓ *Others surfaces:*

- *Walls: wet sweep, do not rinse **
- *Furniture, sanitary: wet wiping, do not rinse **
- *Cleaning equipment: rinsing, wet wiping, do not rinse **
- *Siphons: pour a dose, leave in contact for 15 minutes before running water*

*** In the case of disinfection of surfaces likely to come into direct contact with food, rinsing with drinking water is necessary (in accordance with the decree of September 8, 1999 and its modifications).*

5. Activité nettoyante et détergente */ Cleaning and detergent activity*

L'efficacité détergente du PHAGO'SURF 2D pour le nettoyage des surfaces est assurée par le complexe détergent non ionique et le système tampon qui permettent une élimination efficace et sans peine des salissures sans laisser de traces.

*The detergent efficiency of **PHAGO'SURF 2D** for cleaning of surfaces is ensured by the nonionic detergent complex and the buffer system which allow efficient and effortless removal of dirt without leaving traces.*

6. Activité antimicrobienne / *Antimicrobial activity*

Activité Activity	NORMES Standards	Souches Strains	Concentration Concentration	Temps Time	Rapport (N°, Date) Report (N°, Date)	Laboratoire Laboratory
Bactéricide *Bactericidal*	**EN 13727+A1** (2013) Conditions de saleté/*Dirty conditions*	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	0,25%	5 min.	3583-1 05/05/2018	Laboratoire Rivadis
	EN 13697 (2015) Conditions de saleté/*Dirty conditions*	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	0,25%	15 min.	05/01/2009	Blu Scientific
	EN 16615 (2015) Conditions de saleté/*Dirty conditions*	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	0,25%	15 min.	S103/2019 01/07/2019	CHEMILA
Levuricide *levuricidal*	**EN 13624** (2013) Conditions de saleté/*Dirty conditions*	*Candida albicans*	0,25%	15 min.	3584-1 11/05/2015	Laboratoire Rivadis
	EN 13697 (2015) Conditions de saleté/*Dirty conditions*	*Candida albicans*	0,25%	15 min.	05/01/2009	Blu Scientific
	EN 16615 (2015) Conditions de saleté/*Dirty conditions*	*Candida albicans*	0,25%	15 min	S265-1/2018 25/02/2019	CHEMILA
Fongicide *Fungicidal*	**EN 16615** (2015) Conditions de saleté/*Dirty conditions*	*Aspergillus brasiliensis*	0,25%	15 min	S265-1/2018 25/02/2019	CHEMILA
Tuberculocide *Tuberculocidal*	**EN 14348** (2005) Conditions de saleté/*Dirty conditions*	*Mycobacterium terrae*	0,25%	30 min.	SD2519 08/02/2019	Nordic Tersus Laboratory
virucide *Virucidal*	**EN 14476+A1** (2015) Conditions de saleté/*Dirty conditions*	BVDV	0,25%	15 min.	17/000143434 11/04/2017	CHELAB
	EN 16777 (2018) Conditions de saleté/*Dirty conditions*	Vaccinia virus	0,25%	15 min.	S62-2/2019 31/10/2019	CHEMILA

7. Compatibilités / *Compatibility*

L'étude de compatibilité est réalisée par immersion en continu des matériaux durant 200 heures dans une solution diluée à 0,5% de PHAGO'SURF 2D.
Le Tableau récapitulatif des essais de compatibilité entre **PHAGO'SURF 2D** et les différents matériaux constitutifs de ces dispositifs médicaux et des surfaces est disponible ci-dessous.

*The compatibility study is carried out by continuously immersing the materials for 200 hours in a 0.25% diluted solution of **PHAGO'SURF 2D**.*
*The summary table of the compatibility tests between **PHAGO'SURF 2D** and the various constituent materials of these medical devices and surfaces is available below.*

Matériaux *Materials*	Après 200 heures de trempage *After 200 hours of soaking*
Acier inoxydable 1,4301 *Stainless steel 1.4301*	Compatible
Acier inoxydable 1,4404 *Stainless steel 1.4404*	Compatible
Aluminium 2017A *Aluminium 2017A*	Compatible
Aluminium 5754 *Aluminium 5754*	Compatible
Aluminium anodisé 5005A *Anodized aluminium 5004A*	Compatible
Caoutchouc Butadiène-acrylonitrile (NBR) *Nitrile butadiene rubber (NBR)*	Compatible
Caoutchouc butyle (IIR) *(Butyl rubber) (IIR)*	Compatible
Cuivre *Copper*	Compatible
Ethylène propylène diène monomer (EPDM)	Compatible
Fluoroélastomère (FPM/FKM) type VITON® *Fluorinated rubber (FPM/FKM) type VITON®*	Compatible
Laiton MS63 *Brass MS63*	Compatible
PMMA Röhm Plexiglas XT 20070FF	Compatible
PMMA Röhm Plexiglas GS	Compatible
Polycarbonate Makroform 099	Compatible
Polychlorure de vinyle (PVC) *Polyvinyl chloride (PVC)*	Compatible
Polyéthylène haute densité (PEHD) *High density polyethylene (HDPE)*	Compatible
Polypropylène (PP) *Polypropylene (PP)*	Compatible
Polytéréphtalate d'éthylène (PET) *Polyethylene terephthalate (PET)*	Compatible
Polyuréthane (PU)	Compatible
Titane *Titanium*	Compatible

Ne pas mélanger aux aldéhydes ou pulvériser sur des surfaces préalablement traitées avec cette classe chimique (risque de coloration en rouge).
Ne pas mélanger avec des produits contenant des tensio-actifs anioniques.
En cas de doute sur la compatibilité du **PHAGO'SURF 2D**, contacter votre représentant commercial et/ou réaliser au préalable un test sur une petite surface.

Do not mix with aldehydes or spray on surfaces previously treated with this chemical class (risk of red coloring).
Do not mix with products containing anionic surfactants.
If in doubt about the compatibility of the PHAGO'SURF 2D, contact your sales representative and / or carry out a test on a small area beforehand.

8. Règlementation - conduites d'urgence / *Regulation – emergency procedures*

Règlementation produit :

Le **PHAGO'SURF 2D** est formulé conformément aux réglementations en vigueur au sein de l'Union Européenne et de la France relatives aux biocides et aux détergents.

Conduites d'urgence :

Utiliser les Biocides avec précautions. Avant toute utilisation, lire l'étiquette et les informations concernant le produit.
La fiche de données de sécurité est à la disposition des utilisateurs sur le site http://www.quickfds.com.
En cas d'ingestion accidentelle, ne pas faire vomir, ne rien donner à boire. Consulter un médecin.
En cas de contact du produit pur avec les yeux, rincer immédiatement à l'eau en maintenant les paupières écartées. Consulter un spécialiste en cas d'irritation persistante.
Numéro national d'appel d'urgence ORFILA : 01 45 42 59 59

Product regulation :

PHAGO'SURF 2D is formulated in accordance with European Union and French regulations concerning biocides and detergents.

Emergency procedures :

Use biocides carefully. Before use, read the label and product information.
The safety data sheet is available to users at http://www.quickfds.com .
If accidentally swallowed, do not induce vomiting, nor anything to drink. Consult a doctor.
In case of contact of the pure product with the eyes, rinse immediately with water, holding the eyelids apart. Consult a specialist in case of persistent irritation.
In case of emergency contact the local poison control center.

9. Stabilité et conditions de stockage / Stability and storage conditions

Stockage dans le flacon d'origine, en position verticale.
Stockage entre +4°C et +40°C, à l'abri de la chaleur et du gel.
Le numéro de lot et la date de péremption sont imprimés directement sur le flacon.
Stabilité :

- Bidon non ouvert : 2 ans à partir de la date de production.
- Bidon ouvert : conservation du produit en récipient fermé : maintien de la durée de 2 ans.

Les solutions diluées sont stables 45 jours (conservation des propriétés antimicrobiennes) dans un récipient fermé et stocké à température ambiante.

Storage in original bottle, in a vertical position
Storage between +4°C and +40°C, away from heat and frost.
The batch number and expiry date are printed directly on the bottle.
Stability:

- *Non opened bottle: 2 years from the manufacturing date.*
- *Opened bottle: preserving of the 2 years if the product is stored in a container closed after use.*

Diluted solutions are stable for 45 days (retention of antimicrobial properties) in a closed container and stored at room temperature.

10.Conditionnements / *Packaging*

Présentation *Presentation*	Code	Nombre d'unités par carton *Number of units per carton*
Dose / *Pod* 20ml	60424	250 unités / *units*
Flacon / *Bottle* 1L	60428	6 unités / *units*
Bidon / *Can* 5L	60423	2 unités / *units*

11.Annexes / *Appendices*

CHRISTEYNS

Je soussigné, Jérôme DUBOURGEOIS, Responsable Recherche & Développement santé de la société Christeyns France certifie que les produits suivants ont une composition similaire :

I, Jérôme DUBOURGEOIS, Health Research & Development Manager of Christeyns France hereby certify that the following products have a strictly identical formula:

DETERGENT DESINFECTANT SOLS ET SURFACES AL3236

F173

et/*and*

PHAGO'SURF 2D

La différence de formulation porte sur la suppression du parfum et la substitution du séquestrant.
Ces modifications ont été validées par la réalisation de la norme EN 16615 sur Myc*obacterium terrae* et *Aspergillus brasiliensis* considérées comme souches limitantes pour ce produit.
Le Phago'surf 2D est efficace à 0,25% en 15 minutes sur ces souches.

The difference in formulation relates to the removal of the fragrance and the substitution of the sequestrant.
These modifications were validated by the realization of the standard EN 16615 on Mycobacterium terrae and Aspergillus brasiliensis considered as limiting strains for this product.
Phago'surf 2D is effective at 0.25% in 15 minutes on these strains.

Vertou, 23/11/2020

Jérôme DUBOURGEOIS
Senior Research Associate

Christeyns France S.A. 31 rue de la Maladrie 44 120 VERTOU
T +33 2 40 80 27 27 **E** info@christeyns.com **E** www.christeyns.com
RCS NANTES B 321 302 689 00013 | APE 2041Z

RAPPORT D'ESSAI N°3583-1

55 Boulevard Jules Verger
35803 DINARD Cedex
Tél. 02 99 16 50 72
Fax. 02 99 16 52 75

Imprimé le : 05/05/15
Date de 1ère impression : 05/05/15

TEST D'EFFICACITE BACTERICIDE
SELON LA NORME NF EN 13727+A1 (Décembre 2013)
F173
Application = Désinfection des surfaces
(Méthode par dilution/neutralisation)

DESTINATAIRE : CHRISTEYNS FRANCE

I- IDENTIFICATION DU DONNEUR D'ORDRE

Mr Jérôme DUBOURGEOIS
CHRISTEYNS FRANCE
31 rue de la Maladrie
44120 VERTOU
Tél. 02-40-80-27-27 - Fax. 02-40-03-09-73

L'accréditation de la section Essais du COFRAC atteste de la compétence des Laboratoires pour les seuls essais couverts par l'accréditation. Si des modifications particulières ont été introduites dans la méthode d'essai indiquée, ces modifications ou spécifications sont précisées dans le paragraphe Commentaires en fin du rapport d'essai

Ce rapport d'essai ne concerne que le produit soumis à l'essai

La reproduction de ce rapport d'essai n'est autorisée que sous forme d'un fac-similé photographique intégrale.

Il comporte 8 pages (cette page comprise).

RAPPORT D'ESSAI N°3583-1

55 Boulevard Jules Verger
35803 DINARD Cedex
Tél. 02 99 16 50 72
Fax. 02 99 16 52 75

II- IDENTIFICATION DE L'ECHANTILLON

- Nom du produit : **F173**
- Numéro de lot : 150129/0846
- Fabricant : CHRISTEYNS FRANCE
- Date de fabrication : 29/01/2015
- Date de péremption : 30/01/2018
- Date de réception au laboratoire : 06/03/15
- Aspect du produit : Liquide limpide jaune
- Conditions de stockage : à température ambiante et à l'abri de la lumière
- Diluant du produit recommandé par le fabricant : eau du réseau
- Matière(s) active(s) : Non communiquées

III- METHODE D'ESSAI

Norme NF EN 13727+A1 (Décembre 2013) : Essai quantitatif de suspension pour l'évaluation de l'activité bactéricide en médecine. (Phase 2, Etape 1).

Application « Désinfection surfaces » : Réduction logarithmique au moins égale à 5 Log décimaux dans les conditions de l'essai.

Neutralisant : 3% Polysorbate 80 ; 3% Saponine ; 0,3% Lécithine d'œuf ; 0,1% L-Histidine ; 0,5% Thiosulfate de sodium (stérilisé à 121°C pendant 20 minutes).

RAPPORT D'ESSAI N°3583-1

55 Boulevard Jules Verger
35803 DINARD Cedex
Tél. 02 99 16 50 72
Fax. 02 99 16 52 75

IV- CONDITIONS EXPERIMENTALES

- Période d'analyse : du 09/04/15 au 13/04/15
- Analyse réalisée par : M.TEULIER
- Diluant du produit utilisé au cours de l'essai : eau dure 30°f
- Concentrations de produit testé (V/V) : 0,125% - 0,25% et 0,5%
- Technique d'essai : dilution/neutralisation
- Aspect des dilutions : limpides
- Stabilité du mélange substance interférente/dilutions du produit : absence de précipité au cours de l'essai
- Temps de contact : 5 minutes (+/- 10 secondes)
- Température d'essai : 20°C (+/-1°C)
- Substance interférente : 3 g/l d'albumine bovine + 3 ml/l d'érythrocytes de mouton (conditions de saleté)
- Température d'incubation : 37°C (+/-1°C)
- Identification des souches utilisées :
  Enterococcus hirae DSM 3320
  Staphylococcus aureus DSM 799
  Pseudomonas aeruginosa DSM 939

RAPPORT D'ESSAI N°3583-1

55 Boulevard Jules Verger
35803 DINARD Cedex
Tél. 02 99 16 50 72
Fax. 02 99 16 52 75

V- RESULTATS D'ESSAI

Vc : nombre de colonies comptées sur les boîtes,
N: nombre d'UFC / ml dans la suspension microbienne d'essai,
N_0: nombre de cellules par ml dans le mélange d'essai au début du temps de contact, il représente un dixième de N,
Nv : nombre de cellules par ml de la suspension microbienne de validation,
Nv_0 : nombre de cellules par ml dans les mélanges A, B et C au début du temps de contact. Il représente un dixième de Nv,
Nv_B : dans le cas du témoin de neutralisant B, il s'agit du nombre de cellules par ml après dilution au centième. Il représente un millième de Nv,
Na : nombre de survivants par ml dans le mélange d'essai à l'issue du temps de contact et avant neutralisation
A : nombre de survivants dans le témoin des conditions expérimentales,
B : nombre de survivants dans le témoin de neutralisant,
C : nombre de survivants dans le témoin de validation de la méthode,
R : réduction du nombre de cellules viables ($R=N_0/Na$) exprimé en logarithme

RAPPORT D'ESSAI N°3583-1

55 Boulevard Jules Verger
35803 DINARD Cedex
Tél. 02 99 16 50 72
Fax. 02 99 16 52 75

Imprimé le : 05/05/15
Date de 1ère impression : 05/05/15

Essai sur *Enterococcus hirae DSM 3320*

Souche testée	Suspension bactérienne d'essai	Essai de validation				
		Suspension bactérienne (NV)	Suspension bactérienne (NVB)	Conditions expérimentales (A)	Non toxicité du neutralisant (B)	Inactivation par dilution/neutralisation (C)
Enterococcus hirae DSM 3320 Lot 568	10^{-6} : Vc1 :240 Vc2 : 274 10^{-7} : Vc1 : 28 Vc2 : 33 N= 2,61.10^8 N_0= 2,61.10^7 Log N_0 = 7,42	Vc1 : 77 Vc2 : 90 (dilution 10^{-1}) Nv= 835 Nv_0= 84	Vc1 : 86 Vc2 : 77 (dilution 10^{-3}) NvB= 8,15.10^4	Vc1 : 80 Vc2 : 79 A= 80	Vc1 : 88 Vc2 : 83 B= 86	Vc1 : 91 Vc2 : 78 C= 85

L'essai est validé si :
N est compris entre 1,5.10^8 et 5.10^8 UFC/ml (8,17 ≤ lg N ≤ 8,70)
N_0 est compris entre 1,5.10^7 et 5.10^7 UFC/ml (7,17 ≤ lg N ≤ 7,70)
Nv_0 est compris entre 30 et 160 UFC/ml (N_v est compris entre 300 et 1600 UFC/ml)
Nv_B est compris entre 3,0.10^4 et 1,6.10^5
A,B et C sont supérieurs ou égaux à 0,5xNv_0
B (dilution-neutralisation) est égal ou supérieur à 0,0005 x Nv_B
Le quotient des dénombrements obtenus par moyenne pondérée est compris entre 5 et 15

Souche testée	Concentrations testées % (V/V)					
	0,125%		0,25%		0,5%	
	10^0	10^{-1}	10^0	10^{-1}	10^0	10^{-1}
Enterococcus hirae DSM 3320 Lot 568 — Vc1 Vc2	0 0	0 0	0 0	0 0	0 0	0 0
Na	<140		<140		<140	
lg Na	<2,15		<2,15		<2,15	
Lg R	>5,27		>5,27		>5,27	

RAPPORT D'ESSAI N°3583-1

55 Boulevard Jules Verger
35803 DINARD Cedex
Tél. 02 99 16 50 72
Fax. 02 99 16 52 75

Essai sur *Staphylococcus aureus DSM 799*

Souche testée	Suspension bactérienne d'essai	Essai de validation				
		Suspension bactérienne (NV)	Suspension bactérienne (NVB)	Conditions expérimentales (A)	Non toxicité du neutralisant (B)	Inactivation par dilution/neutralisation (C)
Staphylococcus aureus DSM 799 Lot 567	10^{-6} : Vc1 : 188 Vc2 : 204 10^{-7} : Vc1 : 18 Vc2 : 35 N= 2,02.10^8 N_0= 2,02.10^7 Log N_0 = 7,31	Vc1 : 65 Vc2 : 68 (dilution 10^{-1}) Nv= 665 Nv_0= 67	Vc1 : 68 Vc2 : 56 (dilution 10^{-3}) NvB= 6,2.10^4	Vc1 : 80 Vc2 : 79 A= 80	Vc1 : 81 Vc2 : 97 B= 89	Vc1 : 69 Vc2 : 71 C= 70

L'essai est validé si :
N est compris entre 1,5.10^8 et 5.10^8 UFC/ml (8,17 ≤ lg N ≤ 8,70)
N_0 est compris entre 1,5.10^7 et 5.10^7 UFC/ml (7,17 ≤ lg N ≤ 7,70)
Nv_0 est compris entre 30 et 160 UFC/ml (N_v est compris entre 300 et 1600 UFC/ml)
Nv_B est compris entre 3,0.10^4 et 1,6.10^5
A,B et C sont supérieurs ou égaux à 0,5xNv_0
B (dilution-neutralisation) est égal ou supérieur à 0,0005 x Nv_B
Le quotient des dénombrements obtenus par moyenne pondérée est compris entre 5 et 15

Souche testée	Concentrations testées % (V/V)						
		0,125%		0,25%		0,5%	
		10^0	10^{-1}	10^0	10^{-1}	10^0	10^{-1}
Staphylococcus aureus DSM 799 Lot 567	Vc1 Vc2	0 0	0 0	0 0	0 0	0 0	0 0
	Na	<140		<140		<140	
	lg Na	<2,15		<2,15		<2,15	
	Lg R	>5,16		>5,16		>5,16	

RAPPORT D'ESSAI N°3583-1

55 Boulevard Jules Verger
35803 DINARD Cedex
Tél. 02 99 16 50 72
Fax. 02 99 16 52 75

Pseudomonas aeruginosa DSM 939

Souche testée	Suspension bactérienne d'essai	Essai de validation				
		Suspension bactérienne (NV)	Suspension bactérienne (NVB)	Conditions expérimentales (A)	Non toxicité du neutralisant (B)	Inactivation par dilution/neutralisation (C)
Pseudomonas aeruginosa DSM 939 Lot 556	10^{-6} : Vc1 : 238 Vc2 : 228 10^{-7} : Vc1 : 20 Vc2 : 31 N= 2,35.10^8 N_0= 2,35.10^7 Log N_0 = 7,37	Vc1 : 66 Vc2 : 81 (dilution 10^{-1}) Nv= 735 Nv_0= 74	Vc1 : 85 Vc2 : 72 (dilution 10^{-3}) NvB= 7,85.10^4	Vc1 : 58 Vc2 : 64 A= 61	Vc1 : 87 Vc2 : 96 B= 92	Vc1 : 88 Vc2 : 82 C= 85

L'essai est validé si :
N est compris entre 1,5.10^8 et 5.10^8 UFC/ml (8,17 ≤ lg N ≤ 8,70)
N_0 est compris entre 1,5.10^7 et 5.10^7 UFC/ml (7,17 ≤ lg N ≤ 7,70)
N_{v0} est compris entre 30 et 160 UFC/ml (N_v est compris entre 300 et 1600 UFC/ml)
Nv_B est compris entre 3,0.10^4 et 1,6.10^5
A,B et C sont supérieurs ou égaux à 0,5xN_{v0}
B (dilution-neutralisation) est égal ou supérieur à 0,0005 x Nv_B
Le quotient des dénombrements obtenus par moyenne pondérée est compris entre 5 et 15

Souche testée		Concentrations testées % (V/V)					
		0,125%		0,25%		0,5%	
		10^0	10^{-1}	10^0	10^{-1}	10^0	10^{-1}
Pseudomonas aeruginosa DSM 939 Lot 556	Vc1 Vc2	>330 >330	>330 >330	0 0	0 0	0 0	0 0
	Na	>3,3.10^4		<140		<140	
	lg Na	>4,52		<2,15		<2,15	
	Lg R	<2,85		>5,22		>5,22	

RAPPORT D'ESSAI N°3583-1

55 Boulevard Jules Verger
35803 DINARD Cedex
Tél. 02 99 16 50 72
Fax. 02 99 16 52 75

VI- CONCLUSION

Conformément à la norme NF EN 13727 + A1 (Décembre 2013), le lot 150129/0846 du produit F173 de la société CHRISTEYNS FRANCE, dans les conditions d'essai suivantes :

- en 5 minutes de temps de contact,
- à la température de 20°C,
- en présence d'albumine bovine à 3 g/l + 3 ml/l d'érythrocytes de mouton (conditions de saleté),

présente une activité bactéricide (réduction supérieure à 5 log décimaux dans le cas de l'application « désinfection de surfaces »), lorsqu'il est dilué à :

- 0,125%, 0,25% et 0,5% (V/V), vis-à-vis des souches *Enterococcus hirae* DSM 3320 et *Staphylococcus aureus* DSM 799,
- 0,25% et 0,5% (V/V) vis-à-vis de la souche *Pseudomonas aeruginosa DSM 939.*

Dans ces conditions d'essais, les concentrations efficaces du lot 150129/0846 du produit F173 sont au final de 0,25% et 0,5% (V/V).

Les souches sont conservées et contrôlées selon la norme NF EN 12353.
Les souches d'essai ont été soumises à essai une seule fois.

VII-SIGNATURES

Fait à DINARD, le 06/05/15

Rédigé par	Validé par
M.TEULIER Responsable d'essai	M.SESQUES Docteur en microbiologie Directeur technique

BluScientific Test Data

Test Report EN13697. Chemical disinfectants and antiseptics — Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas — Test method and requirements without mechanical action (phase 2/step 2).

Test Laboratory	**BluScientific Test Data** School of Life Sciences Glasgow Caledonian University GLASGOW G4 0BA
Identification of sample	
Name of the product	**DETERGENT DESINFECTANT SOLS ET SURFACES**
Batch No.	**AL3236 (20 kg – 10/7/08)**
Manufacturer	LABORATOIRES RIVADIS 79 100 THOUARS, FRANCE
Date of Delivery	21 NOVEMBER 2008
Storage conditions	4°C and darkness
Active substances	Not known
Test Method and its validation	
Neutralizer	Lecithin 3g/l, Polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/l, phosphate buffer 0.0025mol/l, sterilized by autoclave
Experimental Conditions	
Period of analysis	16 – 18 DECEMBER 2008
Product diluent used	Sterile, synthetic, hard water
Product test concentrations	0.0625% V/V; 0.125% V/V; 0.25% V/V
Appearance product dilutions	Clear
Contact time	t = 15 min ± 10 s
Test temperature	20 °C ± 1°C
Interfering substance	3.0g/l bovine albumin
Stability of mixture	No precipitation
Temperature of incubation	37°C ± 1°C
Identification of strains	*Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* ATCC 10536 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541

Conclusion

According to testing carried out under conditions specified in EN13697:2001, **RIVADIS DETERGENT DESINFECTANT SOLS ET SURFACES BATCH NO. AL3236 (20 kg – 10/7/08)** possesses bactericidal activity after 15 minutes at 20°C under **DIRTY** conditions (3.0g/l bovine albumin) at a concentration of 0.25% V/V for referenced strains *Pseudomonas aeruginosa* ATCC 15442, *Escherichia coli* ATCC 10536, *Staphylococcus aureus* ATCC 6538 and *Enterococcus hirae* ATCC 10541.

Signed

Dr Chris Woodall, Director,
BluScientific Test Data, 5 January 2009

School of Life Sciences, Glasgow Caledonian University, Glasgow G4 0BA, Scotland, UK
T: +44 (0) 141 331 8245 M: +44 (0) 7989 96 48 11 F: +44 (0) 141 331 3208
E: info@bluscientific.com W: www.bluscientific.com

BluScientific Test Data

EN 13697 2001:RIVADIS Detergent Disinfectant sols et surfaces, tested under dirty conditions with an exposure time of 15 minutes

Test organisms	Bacterial test suspension	Validation test		Water control	Test procedure at concentrations % V/V of the working concentration		
		NT	NC	Nc	0.0625	0.125	0.25
Pseudomonas aeruginosa **ATCC 15442**	10^{-6}: >300; >300 10^{-7}: 51; 46 N: 7.39	10^{-3}: 8; 14 10^{-4}: 2; 1 10^{-5}: 0; 0 NT: 5.04	10^{-3}: 18; 20 10^{-4}: 0; 2 10^{-5}: 0; 0 NC: 5.28	10^{-3}: 31; 38 10^{-4}: 4; 1 10^{-5}: 1; 0 10^{-6}: 0; 0 Nc: 5.54 Nts: 137	10^{-1}: >300; >300 10^{-2}: 97; 116 Nd: 5.03 Nts: 52 ME: 0.51	10^{-1}: 0; 0 10^{-2}: 0; 0 Nd: <0.1 Nts: 0 ME: >5.44	10^{-1}: 0; 0 10^{-2}: 0; 0 Nd: <0.1 Nts: 0 ME: >5.44
Escherichia coli **ATCC 10536**	10^{-6}: 315; 307 10^{-7}: 35; 42 N: 7.19	10^{-3}: 138; 135 10^{-4}: 9; 2 10^{-5}: 0; 0 NT: 6.14	10^{-3}: 109; 119 10^{-4}: 18; 9 10^{-5}: 1; 1 NC: 6.06	10^{-3}: 86; 102 10^{-4}: 11; 11 10^{-5}: 1; 2 10^{-6}: 0; 0 Nc: 5.97 Nts: >300	10^{-1}: 0; 0 10^{-2}: 0; 0 Nd: <2 Nts: 14 ME: >3.97	10^{-1}: 0; 0 10^{-2}: 0; 0 Nd: <0.1 Nts: 0 ME: >5.87	10^{-1}: 0; 0 10^{-2}: 0; 0 Nd: <0.1 Nts: 0 ME: >5.87
Staphylococcus aureus **ATCC 6538**	10^{-6}:>300; >300 10^{-7}: 80; 65 N: 7.56	10^{-3}: >300; >300 10^{-4}: 311; 275 10^{-5}: 31; 39 NT: 7.47	10^{-3}: >300; >300 10^{-4}: 271; 285 10^{-5}: 37; 39 NC: 7.44	10^{-3}: >300; >300 10^{-4}: 250; 239 10^{-5}: 19; 24 10^{-6}: 0; 1 Nc: 7.39 Nts: >300	10^{-1}: >300; >300 10^{-2}: 59; 55 Nd: 4.76 Nts: 5 ME: 2.63	10^{-1}: 0; 0 10^{-2}: 0; 0 Nd: <2 Nts: 66 ME: >5.39	10^{-1}: 0; 0 10^{-2}: 0; 0 Nd: <0.1 Nts: 0 ME: >7.29
Enterococcus hirae **ATCC 10541**	10^{-6}: 188; 208 10^{-7}: 21; 17 N: 7.00	10^{-3}: 269; 251 10^{-4}: 21; 29 10^{-5}: 3; 2 NT: 6.42	10^{-3}: 268; 258 10^{-4}: 29; 29 10^{-5}: 2; 4 NC: 6.42	10^{-3}: 269; 295 10^{-4}: 37; 29 10^{-5}: 3; 4 10^{-6}: 1; 1 Nc: 6.45 Nts: >300	10^{-1}: 0; 0 10^{-2}: 0; 0 Nd: <2 Nts: 91 ME: >4.45	10^{-1}: 0; 0 10^{-2}: 0; 0 Nd: <2 Nts: 26 ME: >4.45	10^{-1}: 0; 0 10^{-2}: 0; 0 Nd: <0.1 Nts: 0 ME: >6.35

School of Life Sciences, Glasgow Caledonian University, Glasgow G4 0BA, Scotland, UK
T: +44 (0) 141 331 8245 M: +44 (0) 7989 96 48 11 F: +44 (0) 141 331 3208 E: info@bluscientific.com W: www.bluscientific.com

GLASGOW CALEDONIAN UNIVERSITY

BluScientific Test Data

Table Definitions

NT - Log_{10} number of colony forming units (cfu) per test surface of the neutralisation test
NC - Log_{10} number of cfu per test surface of the neutralisation control
N_C - Log_{10} number of cfu per test surface of the water control
N - Log_{10} number of cfu per 50ul of the test suspension
Nts - Less than 100cfu/ml for active concentrations
Nd - Log_{10} number of cfu per test surface of the disinfectant test
ME - Microbiocidal Effect

School of Life Sciences, Glasgow Caledonian University, Glasgow G4 0BA, Scotland, UK
T: +44 (0) 141 331 8245 M: +44 (0) 7989 96 48 11 F: +44 (0) 141 331 3208 E: info@bluscientific.com W: www.bluscientific.com

GLASGOW CALEDONIAN UNIVERSITY

Chemila, spol. s r.o., Za Dráhou 4386/3, Hodonín 69501, Phone +420518340919, chemila@chemila.cz
Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025:2005.

Copy No.: 1
Issue No.: 1

Test report No. S103/2019

DETERMINATION OF BACTERICIDAL (EN 16615:2015) ACTIVITY OF THE PRODUCT **F173**

Sample ID: S103/2019
Sample name: **F173**
Client: Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France
Producer: Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France
Sampling point: Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France

Incoming date:
5.3.2019

Delivery date:
1.7.2019

Hodonín, 1.7.2019

TESTING LABORATORY CERTIFIED BY CZECH ACCREDITATION INSTITUTE
Chemila, spol. s r.o.
Za Dráhou 4386/3
695 01 Hodonín
CZ
č. 1273

Ing. Jana Šlitrová, Head of Laboratory

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S103/2019
Rep No: 62
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 26.2.2019
Sample delivered: 5.3.2019
Testing date: 30.4. – 2.5.2019
Delivered amount: 150 ml
Batch No: 181221/0823-01

Subject of testing:
Determination of bactericidal activity of the product.

Identification of the sample:

Name of the product:	**F173**
Batch number:	181221/0823-01
Date of manufacture:	21/12/2018
Expiry date:	2021-11
Manufacturer:	Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France
Incoming date:	5.3.2019
Storage conditions:	5 – 30 °C

Active compounds and concentrations:
CAS 2372-82-9 N-(3-aminopropyl)-N-dodecylpropane-1,3 diamine 5.5 %
CAS 7173-51-5 Didecyldimethylammonium chloride 3.5 %

Experimental conditions:	**Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers** SOP-M-19-00 (EN 16615:2015)
Period of analysis:	30.4. – 2.5.2019
Lab temperature:	20 °C ± 2.5 °C
Temperature of media:	20 °C ± 1 °C
Test method:	dilution neutralization method
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Product diluent:	hard water
Appearance of the product:	light yellow liquid
Water control:	hard water + polysorbate 80
Test concentration:	0.1%, 0.25%
Contact time:	15 min
Interfering substances:	3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)
Test organisms:	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541
Incubation conditions:	37 °C ± 1 °C, 24 (48) hours
Test surface:	PVC with PUR coating, width 2.5 mm, 20 cm x 50 cm. The surface is cleaned by 70% n-propanol. After drying draw 4 squares 5 cm x 5 cm 5 cm apart, mark them as test fields 1 to 4. The drying controls D_{C0} and D_{Ct} are performed on smaller surface (7 cm x 13 cm, 2 squares 5 cm x 5 cm).
Wipe:	17.5 cm x 28 cm, 55% cellulose, 45% polyethylenterephtalate (PET), the wipe is used only once. 30 minutes before testing put the wipe in Petri dish with 16 ml of the product solution. The wet wipe is weighed before and after testing.
Test weight:	granite, lenght 11.9 cm, width 8.2 cm, height 8.4 cm, weight 2.4 kg
Tampons:	sterile, length 150 mm, disposable, tip made of pure cotton without compounds inhibiting or supporting the effect of product solution or growth of microorganisms, producer F.L. Medical
Parafilm:	Parafilm® M, 10.2 cm x 38 m, producer Brand disposable, protecting the horisontal surface and vertical surfaces before contamination during wiping.

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S103/2019
Rep No: 62
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 26.2.2019
Sample delivered: 5.3.2019
Testing date: 30.4. – 2.5.2019
Delivered amount: 150 ml
Batch No: 181221/0823-01
Page: 3

Test procedure:

1. Preparation of the test suspension
2. Determination of CFU in the test suspension
3. Quantitative test on carriers according to EN 16615:2015
4. Incubation and calculation
5. Expression and interpretation of results

Note:
Bactericidal activity – the capability of a product to produce a reduction in the number of viable bacterial cells of relevant organisms under defined conditions on nonporous surface in the field 1 by at least a 5 lg reduction (10^5).
$R = D_{Ct}/ N_a$ or $\lg R = \lg D_{Ct} - \lg N_a$ the reduction in viability, the drying time: 15 – 20 min

The standard:
EN 16615:2015 Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) – Test method and requirements (phase 2, step 2) April 2015
EN ISO 4833-1 Microbiology of the food chain – Horizontal method for the enumeration of microorganisms – Part 1: Colony count at 30 degrees C by the pour plate technique, September 2013

The Number of CFU in the tested product **F173** (SOP-M-07-00 (EN ISO 4833-1)): 0 CFU/ml

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S103/2019
Rep No: 62
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 26.2.2019
Sample delivered: 5.3.2019
Testing date: 30.4. – 2.5.2019
Delivered amount: 150 ml
Batch No: 181221/0823-01

1. Testing the efficacy of chemical disinfectant **F173** on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces

Tab No. 1.1 Verification of methodology, temperature 20°C, dirty conditions

Validation of suspension (N_{V0})				Neutralizer toxicity control (B)				Method validation (C), product conc. 0.25%			
V_{c1}	60	$\Phi_{Nvo} = 52$		V_{c1}	72	$\Phi_B = 51.5$		V_{c1}	38	$\Phi_C = 52.5$	
V_{c2}	44			V_{c2}	31			V_{c2}	67		
$30 \leq \Phi_{Nvo} \leq 160$				$\Phi_B \geq 0.5\ \Phi_{Nvo}$				$\Phi_C \geq 0.5\ \Phi_{Nvo}$			
x	yes		no	x	yes		no	x	yes		no

Tab No. 1.2 Test suspension

Test suspension N	Dilution	V_{c1}	V_{c1}	Test suspension N_0			
$\Phi = 48 \times 10^8 = \lg 9.68$	10^{-7}	> 330	> 330	$N_0 = N/20$, $\lg N_0 = 8.38$			
$9.17 \leq \lg N \leq 9.70$	10^{-8}	62	34	$7.88 \leq \lg N_0 \leq 8.40$			
				x	yes		no

Tab No. 1.2.1 Drying in time 0

Drying control (D_{C0})	Dilution	V_{c1}	V_{c1}	$\lg D_{C0} = \lg (\Phi \times 5 \times 10^5) = 7.93$			
	10^{-5}	168	175	$6.88 \leq \lg D_{C0} \leq 8.40$			
	10^{-6}	18	17				
				x	yes		no

Tab No. 1.2.2 Drying in time t

Drying control (D_{Ct})	Dilution	V_{c1}	V_{c1}	$\lg D_{Ct} = \lg (\Phi \times 5 \times 10^5) = 7.87$			
	10^{-5}	152	143	$6.88 \leq \lg D_{Ct} \leq 8.40$			
	10^{-6}	16	14				
				x	yes		no

Tab No. 1.3.1 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, dirty conditions

Field / contact time (min)	Dilution after test procedure	V_c	$N_W = (\Phi \times 5)$	N_W requirement >10 cfu/25 cm^2
2 / 15	10^0	3	15	yes
3 / 15	10^0	3	15	yes
4 / 15	10^0	4	20	yes

Tab No. 1.3.2.1 Test – the effect of **F173** (Wipe with product solution) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
0.25/15/dirty/2	10^0	0	<14	yes
0.25/15/dirty/3	10^0	0	<14	yes
0.25/15/dirty/4	10^0	0	<14	yes

Tab No. 1.3.2.2 Test – the effect of **F173** (Wipe with product solution) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
0.1/15/dirty/2	10^0	3	15	yes
0.1/15/dirty/3	10^0	0	<14	yes
0.1/15/dirty/4	10^0	0	<14	yes

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S103/2019
Rep No: 62
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 26.2.2019
Sample delivered: 5.3.2019
Testing date: 30.4. – 2.5.2019
Delivered amount: 150 ml
Batch No: 181221/0823-01

Tab No. 1.3.3 Test – the effect of **F173** (Wipe with product solution) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, dirty conditions, field 1

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	lg N_a (Φ x 5)	**lg R (lg D_{Ct} = 7.87)**
0.25/15/dirty/1	10^0	<14	<14	<1.85	**≥ 6.02**
0.1/15/dirty/1	10^{-1}	21	31	3.11	**4.76**

Tab No. 1.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
F173 (Wipe with 0.25% solution)	18.9	17.9	1.0
F173 (Wipe with 0.1% solution)	19.1	17.7	1.4
Wipe with hard water + polysorbate 80	19.1	17.9	1.2

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml in the bacterial test suspension, N_{V0} = the number of cfu/ml in the bacterial test suspension for validation, N_a = the number of viable bacterial cells per ml in the test mixture, A, B, C = the number of viable bacterial cells per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation $R = D_{Ct}/ N_a$ or $\lg R = \lg D_{Ct} - \lg N_a$ the reduction in viability

Prepared by: Mgr. Karolína Světlíková, Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S103/2019
Rep No: 62
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 26.2.2019
Sample delivered: 5.3.2019
Testing date: 30.4. – 2.5.2019
Delivered amount: 150 ml
Batch No: 181221/0823-01

2. Testing the efficacy of chemical disinfectant **F173** on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces

Tab No. 2.1 Verification of methodology, temperature 20°C, dirty conditions

Validation of suspension (N_{V0})				Neutralizer toxicity control (B)				Method validation (C), product conc. 0.25%			
V_{c1}	37	$\Phi_{Nvo} = 41.5$		V_{c1}	33	$\Phi_B = 36.5$		V_{c1}	33	$\Phi_C = 31$	
V_{c2}	46			V_{c2}	40			V_{c2}	29		
$30 \leq \Phi_{Nvo} \leq 160$				$\Phi_B \geq 0.5\ \Phi_{Nvo}$				$\Phi_C \geq 0.5\ \Phi_{Nvo}$			
x	yes		no	x	yes		no	x	yes		no

Tab No. 2.2 Test suspension

Test suspension N	Dilution	V_{c1}	V_{c1}	Test suspension N_0			
$\Phi = 42.5 \times 10^8 = \lg 9.63$	10^{-7}	> 330	> 330	$N_0 = N/20$, $\lg N_0 = 8.33$			
$9.17 \leq \lg N \leq 9.70$	10^{-8}	48	37	$7.88 \leq \lg N_0 \leq 8.40$			
				x	yes		no

Tab No. 2.2.1 Drying in time 0

Drying control (D_{C0})	Dilution	V_{c1}	V_{c1}	$\lg D_{C0} = \lg (\Phi \times 5 \times 10^5) = 7.80$			
	10^{-4}	> 330	> 330	$6.88 \leq \lg D_{C0} \leq 8.40$			
	10^{-5}	132	119				
				x	yes		no

Tab No. 2.2.2 Drying in time t

Drying control (D_{Ct})	Dilution	V_{c1}	V_{c1}	$\lg D_{Ct} = \lg (\Phi \times 5 \times 10^5) = 7.75$			
	10^{-4}	> 330	> 330	$6.88 \leq \lg D_{Ct} \leq 8.40$			
	10^{-5}	109	118				
				x	yes		no

Tab No. 2.3.1 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, dirty conditions

Field / contact time (min)	Dilution after test procedure	V_c	$N_W = (\Phi \times 5)$	N_W requirement >10 cfu/25 cm^2
2 / 15	10^0	5	25	yes
3 / 15	10^0	5	25	yes
4 / 15	10^0	8	40	yes

Tab No. 2.3.2.1 Test – the effect of **F173** (Wipe with product solution) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
0.25/15/dirty/2	10^0	1	<14	yes
0.25/15/dirty/3	10^0	3	15	yes
0.25/15/dirty/4	10^0	3	15	yes

Tab No. 2.3.2.2 Test – the effect of **F173** (Wipe with product solution) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
0.1/15/dirty/2	10^0	0	<14	yes
0.1/15/dirty/3	10^0	2	<14	yes
0.1/15/dirty/4	10^0	0	<14	yes

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S103/2019
Rep No: 62
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 26.2.2019
Sample delivered: 5.3.2019
Testing date: 30.4. – 2.5.2019
Delivered amount: 150 ml
Batch No: 181221/0823-01

Tab No. 2.3.3 Test – the effect of **F173** (Wipe with product solution) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, dirty conditions, field 1

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	lg N_a (Φ x 5)	**lg R ($lg D_{Ct} = 7.75$)**
0.25/15/dirty/1	10^0	17	18	1.94	**5.81**
0.1/15/dirty/1	10^0	78	74	2.58	**5.17**

Tab No. 2.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
F173 (Wipe with 0.25% solution)	19.2	17.9	1.3
F173 (Wipe with 0.1% solution)	19.2	18.0	1.2
Wipe with hard water + polysorbate 80	19.3	18.3	1.0

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml in the bacterial test suspension, N_{V0} = the number of cfu/ml in the bacterial test suspension for validation, N_a = the number of viable bacterial cells per ml in the test mixture, A, B, C = the number of viable bacterial cells per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation $R = D_{Ct}/ N_a$ or $lg R = lg D_{Ct} – lg N_a$ the reduction in viability

Prepared by: Mgr. Karolína Světlíková, Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S103/2019
Rep No: 62
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 26.2.2019
Sample delivered: 5.3.2019
Testing date: 30.4. – 2.5.2019
Delivered amount: 150 ml
Batch No: 181221/0823-01

3. Testing the efficacy of chemical disinfectant **F173** on *Enterococcus hirae* ATCC 10541 on non-porous surfaces

Tab No. 3.1 Verification of methodology, temperature 20°C, dirty conditions

Validation of suspension (N_{V0})			Neutralizer toxicity control (B)			Method validation (C), product conc. 0.25%		
V_{c1}	49	$\Phi_{Nvo} = 45$	V_{c1}	46	$\Phi_B = 43$	V_{c1}	26	$\Phi_C = 38$
V_{c2}	41		V_{c2}	40		V_{c2}	50	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no

Tab No. 3.2 Test suspension

Test suspension N	Dilution	V_{c1}	V_{c1}	Test suspension N_0
$\Phi = 45.5 \times 10^8 = \lg 9.66$	10^{-7}	> 330	> 330	$N_0 = N/20$, $\lg N_0 = 8.36$
$9.17 \leq \lg N \leq 9.70$	10^{-8}	42	49	$7.88 \leq \lg N_0 \leq 8.40$
				x yes no

Tab No. 3.2.1 Drying in time 0

Drying control (D_{C0})	Dilution	V_{c1}	V_{c1}	$\lg D_{C0} = \lg (\Phi \times 5 \times 10^5) = 7.77$
	10^{-4}	> 330	> 330	$6.88 \leq \lg D_{C0} \leq 8.40$
	10^{-5}	110	126	
				x yes no

Tab No. 3.2.2 Drying in time t

Drying control (D_{Ct})	Dilution	V_{c1}	V_{c1}	$\lg D_{Ct} = \lg (\Phi \times 5 \times 10^5) = 7.67$
	10^{-4}	> 330	> 330	$6.88 \leq \lg D_{Ct} \leq 8.40$
	10^{-5}	99	88	
				x yes no

Tab No. 3.3.1 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, dirty conditions

Field / contact time (min)	Dilution after test procedure	V_c	$N_W = (\Phi \times 5)$	N_W requirement >10 cfu/25 cm^2
2 / 15	10^0	18	90	yes
3 / 15	10^0	72	360	yes
4 / 15	10^0	18	90	yes

Tab No. 3.3.2.1 Test – the effect of **F173** (Wipe with product solution) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
0.25/15/dirty/2	10^0	2	<14	yes
0.25/15/dirty/3	10^0	3	15	yes
0.25/15/dirty/4	10^0	0	<14	yes

Tab No. 3.3.2.2 Test – the effect of **F173** (Wipe with product solution) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
0.1/15/dirty/2	10^0	7	35	yes
0.1/15/dirty/3	10^0	0	<14	yes
0.1/15/dirty/4	10^0	0	<14	yes

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S103/2019
Rep No: 62
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 26.2.2019
Sample delivered: 5.3.2019
Testing date: 30.4. – 2.5.2019
Delivered amount: 150 ml
Batch No: 181221/0823-01

Tab No. 3.3.3 Test – the effect of **F173** (Wipe with product solution) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, dirty conditions, field 1

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	lg N_a (Φ x 5)	**lg R (lg D_{Ct} = 7.67)**
0.25/15/dirty/1	10^0	<14	<14	<1.85	**≥ 5.82**
0.1/15/dirty/1	10^0	77	68	2.56	**5.11**

Tab No. 3.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
F173 (Wipe with 0.25% solution)	19.2	18.1	1.1
F173 (Wipe with 0.1% solution)	19.0	17.9	1.1
Wipe with hard water + polysorbate 80	19.4	18.1	1.3

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml in the bacterial test suspension, N_{V0} = the number of cfu/ml in the bacterial test suspension for validation, N_a = the number of viable bacterial cells per ml in the test mixture, A, B, C = the number of viable bacterial cells per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation R = D_{Ct}/ N_a or lg R = lg D_{Ct} – lg N_a the reduction in viability

Prepared by: Mgr. Karolína Světlíková, Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S103/2019
Rep No: 62
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 26.2.2019
Sample delivered: 5.3.2019
Testing date: 30.4. – 2.5.2019
Delivered amount: 150 ml
Batch No: 181221/0823-01

4. Evaluation of bactericidal activity of the product **F173**

Tab No. 4.1 The efficacy of chemical disinfectant **F173** on test strains – bactericidal activity on non-porous surfaces, dirty conditions, field 1

Bactericidal and yeasticidal activity of the product (EN 16615:2015)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances – conditions	lg R EN 16615:2015	**lg R**
Pseudomonas aeruginosa ATCC 15442	20	15	0.25	dirty	≥ 5	**< 5**
Staphylococcus aureus ATCC 6538	20	15	0.25	dirty	≥ 5	**> 5**
Enterococcus hirae ATCC 10541	20	15	0.25	dirty	≥ 5	**> 5**
Pseudomonas aeruginosa ATCC 15442	20	15	0.1	dirty	≥ 5	**> 5**
Staphylococcus aureus ATCC 6538	20	15	0.1	dirty	≥ 5	**> 5**
Enterococcus hirae ATCC 10541	20	15	0.1	dirty	≥ 5	**> 5**

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml in the test suspension, N_{V0} = the number of cfu/ml in the test suspension for validation, N_a = the number of bacteria and fungi per ml in the test mixture, A, B, C = the number of bacteria and fungi per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation $R = D_{Ct}/ N_a$ or $\lg R = \lg D_{Ct} - \lg N_a$ the reduction in viability

Prepared by: Mgr. Karolína Světlíková, Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S103/2019
Rep No: 62
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 26.2.2019
Sample delivered: 5.3.2019
Testing date: 30.4. – 2.5.2019
Delivered amount: 150 ml
Batch No: 181221/0823-01
Page: 11

Interpretation:
Results of tests are in Tabs.
According to EN 16615:2015 the tested product **F173**, batch No. 181221/0823-01, in the concentration 0.25%, diluted in hard water (soaked wipe) and in the contact time 15 min under dirty conditions at temperature 20 °C ± 2.5 °C by the dilution neutralization method **decreased** on non-porous surfaces on field 1 the number of viable bacterial cells of *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541 by at least a 5 lg reduction.

Conclusion:
The product **F173** is capable of reducing the number of viable bacterial cells of the relevant organisms on non-porous surfaces under defined conditions to the declared values and, consequently, may be called bactericidal.

1.7.2019, Hodonín

-2-
Chemila, spol. s r.o.
Za Drážkou 4306/3
695 01 Hodonín

č. 1273

Ing. Barbora Stoklásková, Leader of Study

RAPPORT D'ESSAI N°3584-1

55 Boulevard Jules Verger
35803 DINARD Cedex
Tél. 02 99 16 50 72
Fax. 02 99 16 52 75

TEST D'EFFICACITE LEVURICIDE
SELON LA NORME NF EN 13624 (Novembre 2013)
F173
Application = Désinfection de surface
(Méthode par dilution/neutralisation)

DESTINATAIRE : CHRISTEYNS FRANCE

I- IDENTIFICATION DU DONNEUR D'ORDRE

Mr Jérôme DUBOURGEOIS
CHRISTEYNS FRANCE
31 rue de la Maladrie
44120 VERTOU
Tél. 02-40-80-27-27 - Fax. 02-40-03-09-73

II- IDENTIFICATION DE L'ECHANTILLON

- Nom du produit : **F173**
- Numéro de lot : 150211003
- Fabricant : CHRISTEYNS FRANCE
- Date de fabrication : 11/02/15
- Date de péremption : 11/02/18
- Date de réception au laboratoire : 20/04/15
- Aspect du produit : Liquide limpide jaune
- Conditions de stockage : à température ambiante et à l'abri de la lumière
- Diluant du produit recommandé par le fabricant : eau du réseau
- Matière(s) active(s) : Non communiquées

RAPPORT D'ESSAI N°3584-1

55 Boulevard Jules Verger
35803 DINARD Cedex
Tél. 02 99 16 50 72
Fax. 02 99 16 52 75

III- METHODE D'ESSAI

Norme NF EN 13624 (Novembre 2013) : Essai quantitatif de suspension pour l'évaluation de l'activité fongicide ou levuricide en médecine. (Phase 2, Etape 1).

Application « Désinfection de surface» : Réduction logarithmique au moins égale à 4 Log décimaux dans les conditions de l'essai.

Neutralisant : 3% Polysorbate 80 ; 3% Saponine ; 0,3% Lécithine d'œuf ; 0,1% L-Histidine ; 0,5% Thiosulfate de sodium (stérilisé à 121°C pendant 20 minutes).

IV- CONDITIONS EXPERIMENTALES

- Période d'analyse : du 06/05/15 au 11/05/15
- Analyse réalisée par : M.TEULIER
- Diluant du produit utilisé au cours de l'essai : eau dure
- Concentrations de produit testé (V/V) : 0,125% – 0,25% et 0,5%
- Technique d'essai : dilution/neutralisation
- Aspect des dilutions : Limpides
- Stabilité du mélange substance interférente/dilutions du produit/suspension microbienne : absence de précipité au cours de l'essai
- Temps de contact : 15 minutes (+/-10 secondes)
- Température d'essai : 20°C (+/-1°C)
- Substance interférente : 3 g/l d'albumine bovine et 3 ml/l d'érythrocytes de mouton (conditions de saleté)
- Température d'incubation : 30°C (+/-1°C)
- Identification de la souche utilisée :
  Candida albicans DSM 1386

RAPPORT D'ESSAI N°3584-1

55 Boulevard Jules Verger
35803 DINARD Cedex
Tél. 02 99 16 50 72
Fax. 02 99 16 52 75

V- RESULTATS D'ESSAI

Vc : nombre de colonies comptées sur les boîtes,
N: nombre d'UFC / ml dans la suspension microbienne d'essai,
N_0: nombre de cellules par ml dans le mélange d'essai au début du temps de contact, il représente un dixième de N,
Nv : nombre de cellules par ml de la suspension microbienne de validation,
Nv_0 : nombre de cellules par ml dans les mélanges A, B et C au début du temps de contact. Il représente un dixième de Nv,
Nv_B : dans le cas du témoin de neutralisant B, il s'agit du nombre de cellules par ml après dilution au centième. Il représente un millième de Nv,
Na : nombre de survivants par ml dans le mélange d'essai à l'issue du temps de contact et avant neutralisation
A : nombre de survivants dans le témoin des conditions expérimentales,
B : nombre de survivants dans le témoin de neutralisant,
C : nombre de survivants dans le témoin de validation de la méthode,
R : réduction du nombre de cellules viables ($R=N_0/Na$) exprimé en logarithme

RAPPORT D'ESSAI N°3584-1

55 Boulevard Jules Verger
35803 DINARD Cedex
Tél. 02 99 16 50 72
Fax. 02 99 16 52 75

Essai sur *Candida albicans DSM 1386*

Souche testée	Suspension microbienne d'essai	Essai de validation				
		Suspension microbienne (NV)	Suspension microbienne (NVB)	Conditions expérimentales (A)	Non toxicité du neutralisant (B)	Inactivation par dilution/neutralisation (C) pour 0,5%
Candida albicans DSM 1386 Lot 534	10^{-5} : Vc1 : 271 Vc2 : 257 10^{-6} : Vc1 : 42 Vc2 : 27 N= 2,71.10^7 N_0= 2,71.10^6 Log N_0 =6,43	Vc1 : 82 Vc2 : 78 (dilution 10^{-1}) Nv= 800 Nv_0= 80	Vc1 : 74 Vc2 : 75 (dilution 10^{-3}) Nv_B= 7,45.10^4	Vc1 : 78 Vc2 : 83 A= 81	Vc1 : 69 Vc2 : 67 B= 68	Vc1 : 79 Vc2 : 72 C=76

L'essai est validé si :
N est compris entre 1,5.10^7 et 5.10^7 UFC/ml (7,17 ≤ lg N ≤ 7,70)
N_0 est compris entre 1,5.10^6 et 5.10^6 UFC/ml (6,17 ≤ lg N ≤ 6,70)
Nv_0 est compris entre 30 et 160 UFC/ml (Nv_0 est compris entre 300 et 1600 UFC/ml)
Nv_B est compris entre 3,0.10^4 et 1,6.10^5
A,B et C sont supérieurs ou égaux à 0,5xNv_0
B (dilution-neutralisation) est égal ou supérieur à 0,0005 x Nv_B
Le quotient des dénombrements obtenus par moyenne pondérée est compris entre 5 et 15

Souche testée		Concentrations testées % (V/V)								
		0,125%			0,25%			0,5%		
		10^0	10^{-1}	10^{-2}	10^0	10^{-1}	10^{-2}	10^0	10^{-1}	10^{-2}
Candida albicans DSM 1386 Lot 534	Vc1 Vc2	>330 >330	>330 >330		9 16	1 1		0 0	0 0	
	Na	> 33000			<150			<140		
	lg Na	> 4,52			<2,18			<2,15		
	Lg R	< 1,91			>4,25			>4,28		

RAPPORT D'ESSAI N°3584-1

55 Boulevard Jules Verger
35803 DINARD Cedex
Tél. 02 99 16 50 72
Fax. 02 99 16 52 75

VI- CONCLUSION

Selon la méthodologie de la norme NF EN 13624 (Novembre 2013), le lot 150211003 du produit F173 de la société CHRISTEYNS FRANCE, dans les conditions d'essai suivantes :

- en 15 minutes de temps de contact,
- à la température de 20°C,
- en présence d'albumine bovine à 3 g/l et d'érythrocytes de mouton à 3 ml/l (conditions de saleté) ;

présente une activité levuricide (réduction supérieure à 4 log décimaux dans le cas de l'application « Désinfection de surface »), lorsqu'il est dilué à 0,25% et 0,5% (V/V), vis-à-vis de la souche *Candida albicans* DSM 1386.

La souche est conservée et contrôlée selon la norme NF EN 12353.
La souche d'essai a été soumise à essai une seule fois.

VII-SIGNATURES

Fait à DINARD, le 12/05/15

Rédigé par	Validé par
M.TEULIER Responsable d'essai	M.SESQUES Docteur en microbiologie Directeur technique

BluScientific Test Data

Test Report EN13697 (*Candida albicans*). Chemical disinfectants and antiseptics — Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas — Test method and requirements without mechanical action (phase 2/step 2).

Test Laboratory

BluScientific Test Data
School of Life Sciences
Glasgow Caledonian University
GLASGOW
G4 0BA

Identification of sample

Name of the product	**DETERGENT DESINFECTANT SOLS ET SURFACES**
Batch No.	**AL3236 (20kg – 10/7/08)**
Manufacturer	LABORATOIRES RIVADIS 79 100 THOUARS, FRANCE
Date of Delivery	21 NOVEMBER 2008
Storage conditions	4°C and darkness
Active substances	Not known

Test Method and its validation

Neutralizer	Lecithin 3g/l, Polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/l, phosphate buffer 0.0025mol/l, sterilized by autoclave

Experimental Conditions

Period of analysis	16 – 18 DECEMBER 2008
Product diluent used	Sterile, synthetic, hard water
Product test concentrations	0.0625% V/V; 0.125% V/V; 0.25% V/V
Appearance product dilutions	Clear
Contact time	t = 15 min ± 10 s
Test temperature	20 °C ± 1°C
Interfering substance	3.0g/l bovine albumin
Stability of mixture	No precipitation
Temperature of incubation	30°C ± 1°C
Identification of strains	*Candida albicans* ATCC 10231

Conclusion

According to testing carried out under conditions specified in EN13697:2001, **RIVADIS DETERGENT DESINFECTANT SOLS ET SURFACES BATCH NO. AL3236 (20kg – 10/7/08)** possesses yeastcidal activity after 15 minutes at 20°C under **DIRTY** conditions (3.0g/l bovine albumin) at a concentration of 0.25% V/V for referenced strain *Candida albicans* ATCC 10231.

Signed

Dr Chris Woodall, Director
BluScientific Test Data
5 January 2009

School of Life Sciences, Glasgow Caledonian University, Glasgow G4 0BA, Scotland, UK
T: +44 (0) 141 331 8245 M: +44 (0) 7989 96 48 11 F: +44 (0) 141 331 3208
E: info@bluscientific.com W: www.bluscientific.com

BluScientific Test Data

EN 13697 2001 (*Candida albicans*) : RIVADIS Detergent Disinfectant sols et surfaces, tested under dirty conditions with an exposure time of 15 minutes

Test organisms	Bacterial test suspension	Validation test		Water control	Test procedure at concentrations % V/V of the working concentration		
		NT	NC	Nc	0.0625	0.125	0.25
Candida albicans **ATCC 10231**	10^{-5}: 306; 274 10^{-6}: 11; 14 N: 6.16	10^{-3}: 34; 35 10^{-4}: 2; 2 NT: 5.53	10^{-3}: 21; 26 10^{-4}: 3; 4 NC: 5.38	10^{-3}: 13; 17 10^{-4}: 2; 1 10^{-5}: 0; 0 Nc: 5.17 Nts: 79	10^{-1}: 524; 320 10^{-2}: 42; 38 Nd: 4.62 Nts: 9 ME: 0.55	10^{-1}: 96; 91 10^{-2}: 7; 10 Nd: 3.97 Nts: 3 ME: 1.20	10^{-1}: 1; 8 10^{-2}: 1; 0 Nd: 2.06 Nts: 0 ME: 3.11

Table Definitions

NT - Log_{10} number of colony forming units (cfu) per test surface of the neutralisation test
NC - Log_{10} number of cfu per test surface of the neutralisation control
N_c - Log_{10} number of cfu per test surface of the water control
N - Log_{10} number of cfu per 50ul of the test suspension
Nts - Less than 100cfu/ml for active concentrations
Nd - Log_{10} number of cfu per test surface of the disinfectant test
ME - Microbiocidal Effect

School of Life Sciences, Glasgow Caledonian University, Glasgow G4 0BA, Scotland, UK
T: +44 (0) 141 331 8245 M: +44 (0) 7989 96 48 11 F: +44 (0) 141 331 3208 E: info@bluscientific.com W: www.bluscientific.com

GLASGOW CALEDONIAN UNIVERSITY

Chemila, spol. s r.o., Za Dráhou 4386/3, Hodonín 69501, Phone +420518340919, chemila@chemila.cz
Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025:2005.

Copy No.: 3
Issue No.: 1

Test report No. S265-1/2018

DETERMINATION OF FUNGICIDAL (EN 16615:2015) ACTIVITY OF THE PRODUCT **F173**

Sample ID: S265/2018
Sample name: **F173**
Client: Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France
Producer: Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France
Sampling point: Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France

Incoming date:
10.10.2018

Delivery date:
25.2.2019

Hodonín, 25.2.2019

Ing. Jana Šlitrová, Head of Laboratory

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S265/2018
Rep No: 158
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 22.1. – 25.1.2019
Delivered amount: 800 ml
Batch No: 180613/1617-02

Subject of testing:
Determination of fungicidal activity of the product.

Identification of the sample:

Name of the product:	**F173**
Batch number:	180613/1617-02
Date of manufacture:	12/01/2018
Expiry date:	12/01/2021
Manufacturer:	Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France
Incoming date:	10.10.2018
Storage conditions:	5 – 30 °C

Active compounds and concentrations:
CAS 2372-82-9 N-(3-aminopropyl)-N-dodecylpropane-1,3 diamine 5-10%
CAS 7173-51-5 Didecyldimethylammonium chloride <5 %

Experimental conditions:	**Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers** SOP-M-19-00 (EN 16615:2015)
Period of analysis:	22.1. – 24.1.2019
Lab temperature:	20 °C ± 2.5 °C
Temperature of media:	20 °C ± 1 °C
Test method:	dilution neutralization method
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Product diluent:	hard water
Appearance of the product:	yellow liquid
Water control:	hard water + polysorbate 80
Test concentration:	0.1%, 0.25%, 0.4%
Contact time:	15 min
Interfering substances:	3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)
Test organisms:	*Candida albicans* ATCC 10231
Test organisms:	*Aspergillus brasiliensis (niger)* ATCC 16404*
Incubation conditions:	30 °C ± 1 °C, 48 hours and additional period of 24 or 48 hours
Test surface:	PVC with PUR coating, width 2.5 mm, 20 cm x 50 cm. The surface is cleaned by 70% n-propanol. After drying draw 4 squares 5 cm x 5 cm 5 cm apart, mark them as test fields 1 to 4. The drying controls D_{C0} and D_{Ct} are performed on smaller surface (7 cm x 13 cm, 2 squares 5 cm x 5 cm).
Wipe:	17.5 cm x 28 cm, 55% cellulose, 45% polyethylenterephtalate (PET), the wipe is used only once. 30 minutes before testing put the wipe in Petri dish with 16 ml of the product solution. The wet wipe is weighed before and after testing.
Test weight:	granite, lenght 11.9 cm, width 8.2 cm, height 8.4 cm, weight 2.4 kg
Tampons:	sterile, length 150 mm, disposable, tip made of pure cotton without compounds inhibiting or supporting the effect of product solution or growth of microorganisms, producer F.L. Medical
Parafilm:	Parafilm® M, 10.2 cm x 38 m, producer Brand disposable, protecting the horisontal surface and vertical surfaces before contamination during wiping,

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S265/2018
Rep No: 158
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 22.1. – 25.1.2019
Delivered amount: 800 ml
Batch No: 180613/1617-02

Test procedure:

1. Preparation of the test suspension
2. Determination of CFU in the test suspension
3. Quantitative test on carriers according to EN 16615:2015
4. Incubation and calculation
5. Expression and interpretation of results

Note:
Yeasticidal activity – the capability of a product to produce a reduction in the number of viable yeast cells of *Candida albicans* under defined conditions on nonporous surface in the field 1 by at least 4 orders (10^4).
$R = D_{Ct}/ N_a$ or $\lg R = \lg D_{Ct} - \lg N_a$ the reduction in viability, the drying time: 14 – 37 min
* Strain used according to client's request

The standard:
EN 16615:2015 Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) – Test method and requirements (phase 2, step 2) April 2015

The Number of CFU in the tested product **F173** (SOP-M-07-00 (EN ISO 4833-1)): 0 CFU/ml

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S265/2018
Rep No: 158
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 22.1. – 25.1.2019
Delivered amount: 800 ml
Batch No: 180613/1617-02

1. Testing the efficacy of chemical disinfectant **F173** on *Candida albicans* ATCC 10231 on non-porous surfaces

Tab No. 1.1 Verification of methodology, temperature 20°C, dirty conditions

Validation of suspension (N_{V0})				Neutralizer toxicity control (B)				Method validation (C), product conc. 0.4%			
V_{c1}	55	$\Phi_{Nvo} = 57$		V_{c1}	56	$\Phi_B = 53$		V_{c1}	38	$\Phi_C = 53.5$	
V_{c2}	59			V_{c2}	50			V_{c2}	69		
$30 \leq \Phi_{Nvo} \leq 160$				$\Phi_B \geq 0.5\ \Phi_{Nvo}$				$\Phi_C \geq 0.5\ \Phi_{Nvo}$			
x	yes		no	x	yes		no	x	yes		no

Tab No. 1.2 Test suspension

Test suspension N $\Phi = 257 \times 10^6 = \lg 8.41$ $8.17 \leq \lg N \leq 8.70$	Dilution	V_{c1}	V_{c1}	Test suspension N_0 $N_0 = N/20$, $\lg N_0 = 7.11$ $6.88 \leq \lg N_0 \leq 7.40$			
	10^{-6}	288	220				
	10^{-7}	32	25				
				x	yes		no

Tab No. 1.2.1 Drying in time 0

Drying control (D_{C0})	Dilution	V_{c1}	V_{c1}	$\lg D_{C0} = \lg (\Phi \times 5 \times 10^3) = 6.10$ $5.88 \leq \lg D_{C0} \leq 7.40$			
	10^{-3}	228	284				
	10^{-4}	18	25				
				x	yes		no

Tab No. 1.2.2 Drying in time t

Drying control (D_{Ct})	Dilution	V_{c1}	V_{c1}	$\lg D_{Ct} = \lg (\Phi \times 5 \times 10^3) = 5.88$ $5.88 \leq \lg D_{Ct} \leq 7.40$			
	10^{-3}	151	138				
	10^{-4}	23	20				
				x	yes		no

Tab No. 1.3.1 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Candida albicans* ATCC 10231 on non-porous surfaces, dirty conditions

Field / contact time (min)	Dilution after test procedure	V_c	$N_W = (\Phi \times 5)$	N_W requirement >10 cfu/25 cm^2
2 / 15	10^0	3	15	yes
3 / 15	10^0	4	20	yes
4 / 15	10^0	3	15	yes

Tab No. 1.3.2.1 Test – the effect of **F173** (Wipe with product solution) on *Candida albicans* ATCC 10231 on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
0.4/15/dirty/2	10^0	0	<14	yes
0.4/15/dirty/3	10^0	0	<14	yes
0.4/15/dirty/4	10^0	0	<14	yes

Tab No. 1.3.2.2 Test – the effect of **F173** (Wipe with product solution) on *Candida albicans* ATCC 10231 on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
0.25/15/dirty/2	10^0	0	<14	yes
0.25/15/dirty/3	10^0	0	<14	yes
0.25/15/dirty/4	10^0	0	<14	yes

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S265/2018
Rep No: 158
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 22.1. – 25.1.2019
Delivered amount: 800 ml
Batch No: 180613/1617-02

Tab No. 1.3.2.3 Test – the effect of **F173** (Wipe with product solution) on *Candida albicans* ATCC 10231 on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	N_a = (Φ x 5)	N_a requirement <50 cfu/25 cm^2
0.1/15/dirty/2	10^0	0	<14	yes
0.1/15/dirty/3	10^0	0	<14	yes
0.1/15/dirty/4	10^0	0	<14	yes

Tab No. 1.3.3 Test – the effect of **F173** (Wipe with product solution) on *Candida albicans* ATCC 10231 on non-porous surfaces, dirty conditions, field 1

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	lg N_a (Φ x 5)	**lg R (lg D_{Ct} = 5.88)**
0.4/15/dirty/1	10^0	<14	<14	<1.85	**≥ 4.03**
0.25/15/dirty/1	10^0	<14	<14	<1.85	**≥ 4.03**
0.1/15/dirty/1	10^0	<14	<14	<1.85	**≥ 4.03**

Tab No. 1.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
F173 (Wipe with 0.4% solution)	19.0	17.7	1.3
F173 (Wipe with 0.25% solution)	19.3	18.3	1.0
F173 (Wipe with 0.1% solution)	19.3	17.9	1.4
Wipe with hard water + polysorbate 80	19.2	18.3	0.9

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml in the bacterial test suspension, N_{V0} = the number of cfu/ml in the bacterial test suspension for validation, N_a = the number of viable vegetative yeast cells per ml in the test mixture, A, B, C = the number of viable vegetative yeast cells per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation $R = D_{Ct}/ N_a$ or $\lg R = \lg D_{Ct} - \lg N_a$ the reduction in viability

Prepared by: Ing. Barbora Stoklásková, Lab Technician
Mgr. Karolína Světlíková, Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S265/2018
Rep No: 158
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 22.1. – 25.1.2019
Delivered amount: 800 ml
Batch No: 180613/1617-02

2. Testing the efficacy of chemical disinfectant **F173** on *Aspergillus brasiliensis (niger)* ATCC 16404* on non-porous surfaces

Tab No. 2.1 Verification of methodology, temperature 20°C, dirty conditions

Validation of suspension (N_{V0})				Neutralizer toxicity control (B)				Method validation (C), product conc. 0.4%			
V_{c1}	68	$\Phi_{Nvo} = 56$		V_{c1}	43	$\Phi_B = 46.5$		V_{c1}	62	$\Phi_C = 54.5$	
V_{c2}	44			V_{c2}	50			V_{c2}	47		
$30 \leq \Phi_{Nvo} \leq 160$				$\Phi_B \geq 0.5\ \Phi_{Nvo}$				$\Phi_C \geq 0.5\ \Phi_{Nvo}$			
x	yes		no	x	yes		no	x	yes		no

Tab No. 2.2 Test suspension

Test suspension N	Dilution	V_{c1}	V_{c1}	Test suspension N_0			
$\Phi = 49 \times 10^7 = \lg 8.69$	10^{-6}	> 165	> 165	$N_0 = N/20$, $\lg N_0 = 7.39$			
$8.17 \leq \lg N \leq 8.70$	10^{-7}	46	52	$6.88 \leq \lg N_0 \leq 7.40$			
				x	yes		no

Tab No. 2.2.1 Drying in time 0

Drying control (D_{C0})	Dilution	V_{c1}	V_{c1}	$\lg D_{C0} = \lg (\Phi \times 5 \times 10^4) = 6.30$			
	10^{-3}	> 165	> 165	$5.88 \leq \lg D_{C0} \leq 7.40$			
	10^{-4}	39	40				
				x	yes		no

Tab No. 2.2.2 Drying in time t

Drying control (D_{Ct})	Dilution	V_{c1}	V_{c1}	$\lg D_{Ct} = \lg (\Phi \times 5 \times 10^4) = 6.27$			
	10^{-3}	> 165	> 165	$5.88 \leq \lg D_{Ct} \leq 7.40$			
	10^{-4}	35	39				
				x	yes		no

Tab No. 2.3.1 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Aspergillus brasiliensis (niger)* ATCC 16404* on non-porous surfaces, dirty conditions

Field / contact time (min)	Dilution after test procedure	V_c	$N_W = (\Phi \times 5)$	N_W requirement >10 cfu/25 cm^2
2 / 15	10^0	20	100	yes
3 / 15	10^0	10	50	yes
4 / 15	10^0	3	15	yes

Tab No. 2.3.2.1 Test – the effect of **F173** (Wipe with product solution) on *Aspergillus brasiliensis (niger)* ATCC 16404* on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
0.4/15/dirty/2	10^0	1	<14	yes
0.4/15/dirty/3	10^0	0	<14	yes
0.4/15/dirty/4	10^0	0	<14	yes

Tab No. 2.3.2.2 Test – the effect of **F173** (Wipe with product solution) on *Aspergillus brasiliensis (niger)* ATCC 16404* on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
0.25/15/dirty/2	10^0	2	<14	yes
0.25/15/dirty/3	10^0	3	15	yes
0.25/15/dirty/4	10^0	3	15	yes

* Strain used according to client's request

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S265/2018
Rep No: 158
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 22.1. – 25.1.2019
Delivered amount: 800 ml
Batch No: 180613/1617-02

Tab No. 2.3.2.3 Test – the effect of **F173** (Wipe with product solution) on *Aspergillus brasiliensis (niger)* ATCC 16404* on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	N_a = (Φ x 5)	N_a requirement <50 cfu/25 cm^2
0.1/15/dirty/2	10^0	7	35	yes
0.1/15/dirty/3	10^0	3	15	yes
0.1/15/dirty/4	10^0	1	<14	yes

Tab No. 2.3.3 Test – the effect of **F173** (Wipe with product solution) on *Aspergillus brasiliensis (niger)* ATCC 16404* on non-porous surfaces, dirty conditions, field 1

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	lg N_a (Φ x 5)	**lg R (lg D_{Ct} = 6.27)**
0.4/15/dirty/1	10^0	<14	<14	<1.85	**≥ 4.42**
0.25/15/dirty/1	10^0	<14	<14	<1.85	**≥ 4.42**
0.1/15/dirty/1	10^0	35	51	2.33	**3.94**

Tab No. 2.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
F173 (Wipe with 0.4% solution)	19.2	17.7	1.5
F173 (Wipe with 0.25% solution)	19.4	18.2	1.2
F173 (Wipe with 0.1% solution)	19.4	18.2	1.2
Wipe with hard water + polysorbate 80	19.3	18.4	0.9

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml in the bacterial test suspension, N_{V0} = the number of cfu/ml in the bacterial test suspension for validation, N_a = the number of mould spores per ml in the test mixture, A, B, C = the number of mould spores per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation $R = D_{Ct}/ N_a$ or $\lg R = \lg D_{Ct} - \lg N_a$ the reduction in viability
* Strain used according to client's request

Prepared by: Ing. Barbora Stoklásková, Lab Technician
Mgr. Karolína Světlíková, Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S265/2018
Rep No: 158
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 22.1. – 25.1.2019
Delivered amount: 800 ml
Batch No: 180613/1617-02

3. Evaluation of fungicidal activity of the product **F173**

Tab No. 3.1 The efficacy of chemical disinfectant **F173** on test strains – fungicidal activity on non-porous surfaces, dirty conditions, field 1

Fungicidal activity of the product (EN 16615:2015)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances – conditions	lg R EN 16615:2015	**lg R**
Candida albicans ATCC 10231	20	15	0.4	dirty	≥ 4	**> 4**
Aspergillus brasiliensis (niger) ATCC 16404*	20	15	0.4	dirty	≥ 4	**> 4**
Candida albicans ATCC 10231	20	15	0.25	dirty	≥ 4	**> 4**
Aspergillus brasiliensis (niger) ATCC 16404*	20	15	0.25	dirty	≥ 4	**> 4**
Candida albicans ATCC 10231	20	15	0.1	dirty	≥ 4	**> 4**
Aspergillus brasiliensis (niger) ATCC 16404*	20	15	0.1	dirty	≥ 4	**< 4**

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml in the test suspension, N_{V0} = the number of cfu/ml in the test suspension for validation, N_a = the number of fungi per ml in the test mixture, A, B, C = the number of fungi per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation $R = D_{Ct}/ N_a$ or $lg R = lg D_{Ct} – lg N_a$ the reduction in viability
* Strain used according to client's request

Prepared by: Ing. Barbora Stoklásková, Lab Technician
Mgr. Karolína Světlíková, Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S265/2018
Rep No: 158
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 22.1. – 25.1.2019
Delivered amount: 800 ml
Batch No: 180613/1617-02

Interpretation:
Results of tests are in Tabs.
According to EN 16615:2015 the tested product **F173**, batch No. 180613/1617-02, in the concentrations 0.4%, 0.25% and 0.1%, diluted in hard water (soaked wipe) and in the contact time 15 min under dirty conditions at temperature 20 °C ± 2.5 °C by the dilution neutralization method **decreased** on non-porous surfaces on field 1 the number of viable vegetative yeast cells of *Candida albicans* ATCC 10231 by at least a 4 lg reduction.

According to EN 16615:2015 the tested product **F173**, batch No. 180613/1617-02, in the concentrations 0.4% and 0.25%, diluted in hard water (soaked wipe) and in the contact time 15 min under dirty conditions at temperature 20 °C ± 2.5 °C by the dilution neutralization method **decreased** on non-porous surfaces on field 1 the number of mould spores of *Aspergillus brasiliensis (niger)* ATCC 16404* by at least a 4 lg reduction.

* Strain used according to client's request

Conclusion:
The product **F173** is capable of reducing the number of viable vegetative yeast cells of the relevant organism on non-porous surfaces under defined conditions to the declared values and, consequently, may be called yeasticidal.
The product **F173** is capable of reducing the number of mould spores of the relevant organism on non-porous surfaces under defined conditions to the declared values and, consequently, may be called fungicidal*.
* The test was performed according to client's request

25.2.2019, Hodonín

Ing. Eva Kremlová, Leader of Study

Nordic Tersus
Laboratory

Test report No. sd2519

EVALUATION OF MYCOBACTERICIDAL ACTIVITY OF CHEMICAL DISINFECTANTS IN THE MEDICAL AREA INCLUDING INSTRUMENT DISINFECTANTS (EN 14348)

Name of the product: F173
Batch number: 180613/1617-02
Date of test report: 08.02.2019

Client, representative:
Christeyns France
31 Rue de la Maladrie 44124 Vertou
Jérôme Dubourgeois; +33 (0)2 40 57 56 23

EAK
EESTI AKREDITEERIMISKESKUS
ESTONIAN ACCREDITATION CENTRE
EN ISO/IEC 17025
L263

Nordic Tersus
Laboratory

Test report No. sd2519

EVALUATION OF MYCOBACTERICIDAL ACTIVITY (EN 14348)

Name of the product:	F173
Batch number:	180613/1617-02
Order number:	18018
Manufacturer:	Christeyns France
Client, representative:	Christeyns France; 31 Rue de la Maladrie 44124 Vertou; Jérôme Dubourgeois; +33 (0)2 40 57 56 23
Date of delivery:	12.10.2018
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark;
Active substance – conc.:	Didecyldimethylammonium chloride: 3.5%; Alkylamine: 5.5%
Appearance of the product:	Transparent yellowish liquid
Test concentration:	0.40%; 0.25%; 0.10%
Test conditions:	Dirty conditions
Contact time:	30 min; 60 min (obligatory)
Interfering substance:	3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes
Test neutralizer:	Polysorbate 80, 30 g/l; lecithin, 3 g/l; saponin 30 g/l
Rinsing liquid:	-
Test organisms:	*Mycobacterium terrae* ATCC 15755
Testing method base:	**EVS-EN 14348:2005 – Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1)**
Testing date:	27.12.2018 – 19.01.2018
Results:	look appendix 1-2

.....

Allar Laaneleht
Chief specialist
Date of test report: 08.02.2019

Nordic Tersus Laboratory OÜ
Harjumaa, Tallinn, Serva tn 44a, 11618
Registrikood: 12561442
Tel: +372 503 0197
E-mail: info@ntl.ee

EAK
EESTI AKREDITEERIMISKESKUS
ESTONIAN ACCREDITATION CENTRE
EN ISO/IEC 17025
L263

Appendix 1

TEST RESULTS (mycobactericidal suspension test)

EVS-EN 14348:2005; Phase 2, step 1;
Dilution-neutralization method; Spread plate;
Neutralizer: Polysorbate 80, 30 g/l; lecithin, 3 g/l; saponin 30 g/l
Test organism: *Mycobacterium terrae* ATCC 15755;
Test temperature: +20° C; Incubation temperature: +37° C
Solvents: diluent, water;
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.;
Date of test: 27.12.2018
Responsible person: Allar Laaneleht

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions (A)			Neutralizer control (B)			Method validation (C)		
V_{C1}	62	$\bar{x}$ = 67.5	V_{C1}	47	$\bar{x}$ = 44.5	V_{C1}	43	$\bar{x}$ = 41	V_{C1}	55	$\bar{x}$ = 57.5
V_{C2}	73		V_{C2}	42		V_{C2}	39		V_{C2}	60	
30 ≤ $\bar{x}$ N_{vo} ≤160?yes X; no □			$\bar{x}$ A is ≥ 0,5 $\bar{x}$ N_{vo}?yes X;no □			$\bar{x}$ **B** is ≥ 0,5 $\bar{x}$ N_{vo}? yesX; no □			$\bar{x}$ **C** is ≥ 0,5 $\bar{x}$ N_{vo}? yes X;no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.29 \times 10^9$; log$N$ = 9.36
N and N_0	10^{-7}	**208**	**245**	$N_0 = N/10$; logN_0 = 8.36
	10^{-8}	**23**	**27**	8.17≤ logN_0≤8.7; yes X; no □

Experimental results

Concentration of the product.%	Dilution step	V_{C1}	V_{C2}	log Na	logR	Contact time	Conditions
0.40	10^0	114	132	3.09	5.27	30 min	Dirty
	10^{-1}	<14	<14				
	10^{-2}	<14	<14				
	10^{-3}	<14	<14				
0.40	10^0	17	<14	2.19	6.17	60 min	Dirty
	10^{-1}	<14	<14				
	10^{-2}	<14	<14				
	10^{-3}	<14	<14				
0.25	10^0	>330	>330	3.58	4.78	30 min	Dirty
	10^{-1}	47	29				
	10^{-2}	<14	<14				
	10^{-3}	<14	<14				
0.25	10^0	252	227	3.38	4.98	60 min	Dirty
	10^{-1}	27	24				
	10^{-2}	<14	<14				
	10^{-3}	<14	<14				
0.10	10^0	>330	>330	6.43	1.93	30 min	Dirty
	10^{-1}	>330	>330				
	10^{-2}	>330	>330				
	10^{-3}	279	254				
0.10	10^0	>330	>330	5.90	2.46	60 min	Dirty
	10^{-1}	>330	>330				
	10^{-2}	>330	>330				
	10^{-3}	93	66				

Explanations:

V_C = count per ml (one plate or more)
N = cfu/ml microbes in testsuspension
N_{vo} = cfu/ml in the validation suspension (t=0)
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. duplicate)
N_0 = cfu/ml at the start of the contact time (t=0)
Na = surviving microbes after the test

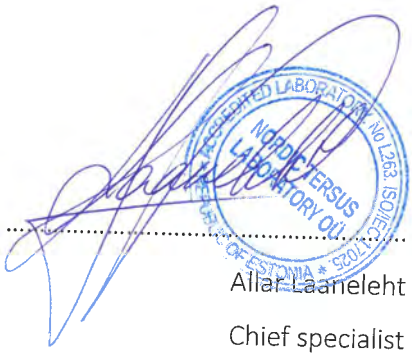
Appendix 2

Interpretation

The EN 14348 standard was used for testing a product **F173** – (Batch No. 180613/1617-02) at 20 °C ± 1 °C, with the contact times 30 min and 60 min (obligatory) under dirty conditions. The dilution-neutralization method was used for testing products' effectiveness against the reference strain: *Mycobacterium terrae* ATCC 15755. Under dirty conditions the tested 0.40% and 0.25% solutions of product were active against the testorganism for both contact times..

Conclusion

The surviving count of mycobacterial reference strains showed at least 4 lg reduction meaning that **under dirty conditions the 0.40% and 0.25% solutions of product F173 are tuberculocidal within 30 min.**



.....

Allar Laaneleht

Chief specialist

08.02.2019

Chemila, spol. s r.o., Za Dráhou 4386/3, Hodonín 69501, Phone +420518340919, chemila@chemila.cz
Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025:2005.

Copy No.: 1
Issue No.: 1

Test report No. S265-3/2018

DETERMINATION OF TUBERCULOCIDAL* (EN 16615:2015) ACTIVITY OF THE PRODUCT **F173**

Sample ID: S265/2018
Sample name: **F173**
Client: Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France
Producer: Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France
Sampling point: Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France

Incoming date:
10.10.2018

Delivery date:
8.4.2019

Hodonín, 8.4.2019

Ing. Jana Šlitrová, Head of Laboratory

* The test with this strain was performed according to the client's request.

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S265/2018
Rep No: 158
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 17.1. – 7.2.2019
Delivered amount: 800 ml
Batch No: 180613/1617-02

Subject of testing:
Determination of tuberculocidal activity of the product.

Identification of the sample:

Name of the product:	**F173**
Batch number:	180613/1617-02
Date of manufacture:	12/01/2018
Expiry date:	12/01/2021
Manufacturer:	Christeyn France S.A., 31, Rue de la Maladrie, 44124 Vertou, France
Incoming date:	10.10.2018
Storage conditions:	5 – 30 °C

Active compounds and concentrations:
CAS 2372-82-9 N-(3-aminopropyl)-N-dodecylpropane-1,3 diamine 5-10%
CAS 7173-51-5 Didecyldimethylammonium chloride <5 %

Experimental conditions:

	Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers SOP-M-19-00 (EN 16615:2015)
Period of analysis:	17.1. – 7.2.2019
Lab temperature:	20 °C ± 2.5 °C
Temperature of media:	20 °C ± 1 °C
Test method:	dilution neutralization method
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Product diluent:	hard water
Appearance of the product:	yellow liquid
Water control:	hard water + polysorbate 80
Test concentration:	0.1%, 0.25%, 0.4%
Contact time:	15 min
Interfering substances:	3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)
Test organisms:	*Mycobacterium terrae* ATCC 15755*
Incubation conditions:	37 °C ± 1 °C, 21 days
Test surface:	PVC with PUR coating, width 2.5 mm, 20 cm x 50 cm. The surface is cleaned by 70% n-propanol. After drying draw 4 squares 5 cm x 5 cm 5 cm apart, mark them as test fields 1 to 4. The drying controls D_{C0} and D_{Ct} are performed on smaller surface (7 cm x 13 cm, 2 squares 5 cm x 5 cm).
Wipe:	17.5 cm x 28 cm, 55% cellulose, 45% polyethylenterephtalate (PET), the wipe is used only once. 30 minutes before testing put the wipe in Petri dish with 16 ml of the product solution. The wet wipe is weighed before and after testing.
Test weight:	granite, lenght 11.9 cm, width 8.2 cm, height 8.4 cm, weight 2.4 kg
Tampons:	sterile, length 150 mm, disposable, tip made of pure cotton without compounds inhibiting or supporting the effect of product solution or growth of microorganisms, producer F.L. Medical
Parafilm:	Parafilm® M, 10.2 cm x 38 m, producer Brand disposable, protecting the horisontal surface and vertical surfaces before contamination during wiping.

* The test with this strain was performed according to the client's request.

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S265/2018
Rep No: 158
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 17.1. – 7.2.2019
Delivered amount: 800 ml
Batch No: 180613/1617-02

Test procedure:

1. Preparation of the test suspension
2. Determination of CFU in the test suspension
3. Quantitative test on carriers according to EN 16615:2015
4. Incubation and calculation
5. Expression and interpretation of results

Note:
Tuberculocidal activity - the capability of a product to produce a reduction in the number of viable cells of *Mycobacterium terrae* under defined conditions by at least a 4 lg reduction (10^4).
$R = D_{Ct}/ N_a$ or $lg\ R = lg\ D_{Ct} - lg\ N_a$ the reduction in viability, the drying time: 40 – 50 min

The standard:
EN 16615:2015 Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) – Test method and requirements (phase 2, step 2) April 2015
EN 14563:2008 Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2) November 2008

The Number of CFU in the tested product **F173**: 0 CFU/ml

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S265/2018
Rep No: 158
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 17.1. – 7.2.2019
Delivered amount: 800 ml
Batch No: 180613/1617-02

1. Testing the efficacy of chemical disinfectant **F173** on *Mycobacterium terrae* ATCC 15755* on non-porous surfaces

Tab No. 1.1 Verification of methodology, temperature 20°C, dirty conditions

Validation of suspension (N_{V0})			Neutralizer toxicity control (B)			Method validation (C), product conc. 0.4%		
V_{c1}	69	$\Phi_{Nvo} = 50.5$	V_{c1}	43	$\Phi_B = 50.5$	V_{c1}	48	$\Phi_C = 38$
V_{c2}	32		V_{c2}	58		V_{c2}	28	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no

Tab No. 1.2 Test suspension

Test suspension N	Dilution	V_{c1}	V_{c1}	Test suspension N_0
$\Phi = 225 \times 10^7 = \lg 9.35$	10^{-7}	228	219	$N_0 = N/20$, $\lg N_0 = 8.05$
$9.17 \leq \lg N \leq 9.70$	10^{-8}	19	29	$7.88 \leq \lg N_0 \leq 8.40$
				x yes no

Tab No. 1.2.1 Drying in time 0

Drying control (D_{C0})	Dilution	V_{c1}	V_{c1}	$\lg D_{C0} = \lg (\Phi \times 5 \times 10^4) = 7.01$
	10^{-4}	207	204	$5.88 \leq \lg D_{C0} \leq 7.40$
	10^{-5}	18	22	
				x yes no

Tab No. 1.2.2 Drying in time t

Drying control (D_{Ct})	Dilution	V_{c1}	V_{c1}	$\lg D_{Ct} = \lg (\Phi \times 5 \times 10^4) = 6.97$
	10^{-4}	184	178	$5.88 \leq \lg D_{Ct} \leq 7.40$
	10^{-5}	19	26	
				x yes no

Tab No. 1.3.1 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Mycobacterium terrae* ATCC 15755* on non-porous surfaces, dirty conditions

Field / contact time (min)	Dilution after test procedure	V_c	$N_W = (\Phi \times 5)$	N_W requirement >10 cfu/25 cm^2
2 / 15	10^{-1}	116	5800	yes
3 / 15	10^0	85	425	yes
4 / 15	10^0	23	115	yes

Tab No. 1.3.2.1 Test – the effect of **F173** (Wipe with product solution) on *Mycobacterium terrae* ATCC 15755* on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
0.4/15/dirty/2	10^0	0	<14	yes
0.4/15/dirty/3	10^0	0	<14	yes
0.4/15/dirty/4	10^0	0	<14	yes

Tab No. 1.3.2.2 Test – the effect of **F173** (Wipe with product solution) on *Mycobacterium terrae* ATCC 15755* on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement <50 cfu/25 cm^2
0.25/15/dirty/2	10^0	81	405	no
0.25/15/dirty/3	10^0	0	<14	yes
0.25/15/dirty/4	10^0	0	<14	yes

* The test with this strain was performed according to the client's request.

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S265/2018
Rep No: 158
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 17.1. – 7.2.2019
Delivered amount: 800 ml
Batch No: 180613/1617-02

Tab No. 1.3.2.3 Test – the effect of **F173** (Wipe with product solution) on *Mycobacterium terrae* ATCC 15755* on non-porous surfaces, dirty conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_c	N_a = (Φ x 5)	N_a requirement <50 cfu/25 cm^2
0.1/15/dirty/2	10^0	37	185	no
0.1/15/dirty/3	10^0	4	20	yes
0.1/15/dirty/4	10^0	0	<14	yes

Tab No. 1.3.3 Test – the effect of **F173** (Wipe with product solution) on *Mycobacterium terrae* ATCC 15755* on non-porous surfaces, dirty conditions, field 1

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	lg N_a (Φ x 5)	**lg R (lg D_{Ct} = 6.97)**
0.4/15/dirty/1	10^0	161	172	2.92	**4.05**
	10^{-1}	17	16		
0.25/15/dirty/1	10^{-2}	100	105	4.71	**2.26**
0.1/15/dirty/1	10^{-2}	145	151	4.88	**2.09**
	10^{-3}	22	17		

Tab No. 1.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
F173 (Wipe with 0.4% solution)	18.8	17.9	0.9
F173 (Wipe with 0.25% solution)	18.3	17.4	0.9
F173 (Wipe with 0.1% solution)	18.8	17.9	0.9
Wipe with hard water + polysorbate 80	19.1	18.1	1.0

2. Evaluation of tuberculocidal* activity of the product **F173**

Tab No. 2.1 The efficacy of chemical disinfectant **F173** on test strains – tuberculocidal* activity on non-porous surfaces, clean conditions, field 1

Tuberculocidal* activity of the product (test procedure according to EN 16615:2015)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances – conditions	lg R reduction according to EN 14563:2008	**lg R**
Mycobacterium terrae ATCC 15755*	20	15	0.4	dirty	≥ 4	**> 4**
Mycobacterium terrae ATCC 15755*	20	15	0.25	dirty	≥ 4	**< 4**
Mycobacterium terrae ATCC 15755*	20	15	0.1	dirty	≥ 4	**< 4**

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml in the test suspension, N_{V0} = the number of cfu/ml in the test suspension for validation, N_a = the number of mycobacteria per ml in the test mixture, A, B, C = the number of mycobacteria per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation R = D_{Ct}/ N_a or lg R = lg D_{Ct} – lg N_a the reduction in viability
* The test with this strain was performed according to the client's request.

Prepared by: Ing. Eva Kremlová, Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S265/2018
Rep No: 158
Sample name: **F173**
Sampled: by client
Sampling point: Christeyn France S.A., Vertou
Client: Christeyn France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 8.10.2018
Sample delivered: 10.10.2018
Testing date: 17.1. – 7.2.2019
Delivered amount: 800 ml
Batch No: 180613/1617-02

Interpretation:
Results of tests are in Tabs.
The tested product **F173**, batch No. 180613/1617-02, in the concentration 0.4%, diluted in hard water (soaked wipe) and in the contact time 15 min under dirty conditions at temperature 20 °C ± 2.5 °C by the dilution neutralization method **decreased** on non-porous surfaces on field 1 the number of viable mycobacterial cells of *Mycobacterium terrae* ATCC 15755* by at least a 4 lg reduction (EN 16615:2015 – test procedure, EN 14563:2008 - evaluation).

Conclusion:
The product **F173** is capable of reducing the number of viable mycobacterial cells of *Mycobacterium terrae** on non-porous surfaces under defined conditions to the declared values and, consequently, may be called tuberculocidal* (EN 16615:2015 – test procedure, EN 14563:2008 - evaluation)
* The test with this strain was performed according to the client's request

8.4.2019, Hodonín

Chemila, spol. s.r.o.
Za Dráhou 4386/3
695 01 Hodonín
CZ
č. 1273

.....
Ing. Barbora Stoklásková, Leader of Study

MERIEUX NutriSciences

CHELAB S.R.L.

LAB N° 0051

TEST REPORT N. 17/000143434

date of issue 11/04/2017

Customer ID 0067822

Messrs
CHRI TE FRA CE A
P 2421
44124 VERT CEDE
Francia

Sample information

Acceptance number 17.581720.0001

Delivered by The Courier on 02/02/2017

Receiving Date 02/02/2017

Place of origin CHRI TE FRA CE A P 2421 44124 VERT CEDE Francia

ample Description F173

Sampling information

ampled by Customer

ANALYTICAL RESULTS

	Value/ ncertain	nit of measure	o	oD	tart/end date of analysis	p. units	ine
ON SAMPLE AS IT IS							1
VIR CIDA ACTIVIT : PE I TE T Met.: I E 14476:2015		view attached file			02/02/2017 11/04/2017	09	2

Operative units

nit 09 : Via Fratta Resana PHARMA TV

iologist responsible
Dott.ssa Federica Cattapan rdine nazionale dei biologi Albo professionale n.045961 sez.A
um. certificato 14114404 emesso dall ente certificatore ArubaPEC .p.A. CA 3, ArubaPEC .p.A., IT

aboratory manager
Dott. bastien Moulard
um. certificato 14114487 emesso dall ente certificatore ArubaPEC .p.A. CA 3, ArubaPEC .p.A., IT

The line mar ed by a star is not accredited by Accredia, member of M A. If not otherwise specified, the uncertainty is extended and has been calculated with a recovery factor 2 corresponding to a probability interval of about 95 . oD is the detection limit and identifies a confidence interval of zero with a probabilty interval of about 99 . o is the limit of uantification."n.d" is not detected and indicates a value inferior to the oD. "traces " means a value between oD and o , this value is indicative. " x" or " x" indicate inferior or superior to the measurement field of the test. If not differently specified, the sums are calculated by lower bound criteria . . . Registration with the number 7 of the Regional ist of the laboratories of the Regione Veneto which perform analyses as regards the procedures for the food safety in food industries, as reported in Annex A of DDR n 73 of 16th anuary 2008 If not differently specified the uantitative microbiological tests excluded MP are performed on single repetition and two consecutive dilutions in accordance to I 7218:2007/Amd1:2013.

Chelab .r.l, a M rieux utri ciences company
Head office: Via Fratta 25 31023 Resana, Italy Phone. + 39 0423.7177 / Fax + 39 0423.715058 www.merieuxnutrisciences.it
VAT nr. 01500900269, R.E.A Treviso n. 156079 Fully paid up € 103.480,00.

UNI EN 14476+A1:2015

Chemical disinfectants and antiseptics
Quantitative suspension test for the evaluation
of virucidal activity in the medical area
(phase 2, step 1)

Sponsor: CHRISTEYNS FRANCE SA
BP 2421
44124 VERTOU CEDEX
Francia

Testing Laboratory: CHELAB SRL MÉRIEUX NUTRISCIENCES,
VIA FRATTA 25,
31023 RESANA (TV)
Italy

- Sample Identification:
  - Product Name: F173
  - Batch n°: 170116/0833-01
  - Expiry date: 12/2019
  - Laboratory Number: 17.581720.0001
- Method used: UNI EN 14476+A1:2015 evaluation of virucidal activity
- Experimental Conditions:
  - Test viruses: Bovine viral diarrhea virus (BVDV) ATCC-VR-534.
  - Cell lines: MDBK, BS CL 63-127 for the propagation of BVDV.
  - Product test concentrations: 0.5 %, 0.25 % and 0.1 % (prepared in distilled water)
  - Interfering substance: Albumine Bovine 3 g/L + 3 ml/L erythrocytes (dirty conditions)
  - Contact time: 15 min ± 10 sec
  - Test temperature: 20 °C ± 1°C
  - Plates incubation temperature: 37°C ± 1°C, 5% CO_2 for 7 days
  - Growth medium: MEM 10% FCS
  - Manteinance medium: MEM 2% FCS
- Test Results: see table n° 1.
- Conclusions: According to UNI EN 14476+A1:2015, under the test conditions applied, the test product has virucidal activity (R ≥ 4) against BVDV at concentrations 0.5 % and 0.25 %. Moreover, the test product has not virucidal activity (R < 4) against BVDV when tested at concentration 0.1 %.

Table 1: Results of the test UNI EN 14476+A1:2015 on BVDV

VIRUS	TEST	SAMPLE	VIRUS TITRATION $logTCID_{50}$	ACCEPTANCE CRITERIA	RESULT
BVDV	TITRATION OF VIRUS CONTROL	0 min	5.75	/	/
		15 min	5.875	/	/
	PRELIMINARY CYTOTOXICITY EFFECT	DONE			
	CELL SUSCEPTIBILITY	CONTROL	5.5	< 1	R = 0.125 PASS
		0.00005% *	5.375		
	EFFICIENCY FOR SUP-PRESSION OF DISINFEC-TANT ACTIVITY	0.5 %	5. 75	≤ 0.5	R = 0.125 PASS
		0.25 %	5.75	≤ 0.5	R = 0.125 PASS
		0.1 %	5.5	≤ 0.5	R = 0.375 PASS
	VIRUCIDAL ACTIVITY	0.5 %	≤ 1.5	R ≥ 4	R ≥ 4.375 ACTIVE
		0.25 %	≤ 1.5	R ≥ 4	R ≥ 4.375 ACTIVE
		0.1 %	5.125	R ≥ 4	R = 0.75 NOT ACTIVE
	REFERENCE VIRUS INACTIVATION TEST	30 MINUTES	3.25	n.a.	R = 2.625
		60 MINUTES	≤ 2.5	n.a.	R ≥ 3.375

* lowest apparently non cytotoxic dilution

Chemila, spol. s r.o., Za Dráhou 4386/3, 695 01 Hodonín, tel. +420 518 340 919, chemila@chemila.cz
Chemical and Microbiological Laboratory

Copy No.: 1
Issue No.: 1

Test report No. S62-2/2019

DETERMINATION OF VIRUCIDAL (EN 16777:2018) ACTIVITY OF THE PRODUCT **F173** ON CARRIERS

Sample ID: S62/2019
Sample name: **F173**
Client: Christeyns France S.A., 31, Rue de la Maladrie, 44124 Vertou, France
Producer: Christeyns France S.A., 31, Rue de la Maladrie, 44124 Vertou, France
Sampling point: Christeyns France S.A., 31, Rue de la Maladrie, 44124 Vertou, France

Incoming date:
13.2.2019

Delivery date:
31.10.2019

Hodonín, 31.10.2019

Chemila, spol. s r.o. -2-
Za Dráhou 4386/3, 695 01 Hodonín
tel.: 518 340 919
IČ: 25304518, DIČ: CZ25304518

.....
Ing. Jana Šlitrová, Head of Laboratory

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S62/2019
Rep No: 49
Sample name: **F173**
Sampled: by client
Sampling point: Christeyns France S.A., Vertou
Client: Christeyns France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 11.2.2019
Sample delivered: 13.2.2019
Testing date: 18.7. – 24.7.2019
Delivered amount: 250 ml
Batch No: 181221/0823-01

Subject of testing:
Determination of virucidal activity of the product.

Identification of the sample:

Name of the product:	**F173**
Batch number:	181221/0823-01
Date of manufacture:	21/12/2018
Expiry date:	2021-11
Manufacturer:	Christeyns France S.A., 31, Rue de la Maladrie, 44124 Vertou, France
Incoming date:	13.2.2019
Storage conditions:	5 – 30 °C
Active compounds and concentrations:	CAS 7173-51-5 didecyldimethylammonium 3.50% CAS 2372-82-9 N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 5.50%

Experiment conditions:	**Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers** SOP-M-22-12 (EN 16777:2018)
Period of analysis:	18.7. – 24.7.2019
Test temperature:	18 °C ± 1 °C to 25 °C ± 1 °C
Method of titration:	virus titration on monolayers of cells on microtitre plates
Product diluent:	hard water
Appearance of the product:	colourless liquid
The test concentration:	0.25%, 0.2%, 0.1%
Contact time:	15 min
Interfering substances:	3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)
Reference product:	Glutardialdehyde (50% solution in water) for synthesis, CAS: 111-30-8, Batch No: S7460593, minimum shelf life 31.01.2021, date of delivery: 6.3.2019 (50 ppm, 5 min, clean conditions)
Test virus:	*Vaccinia virus* strain Elstree CAPM V-160 (3rd passage)
Cell lines:	VERO cells (19th passage)
Carriers:	stainless steel discs stated in the standard
The drying time:	35 min
Incubation:	36 °C ± 1 °C, 5 % CO_2, 96 h, and additional period of 48 hours.

Test procedure: Nine volumes of test virus suspension are mixed with one volume of interfering substance solution. The test surface is prepared by inoculing 50 µl of the virus suspension plus interfering substance. The surfaces are drying until they are visibly dry. The drying time should not exceed 60 min. The test cariers are used within 60 min, to avoid virus inactivation with time. Immediatelly after drying the dried inoculum on the test surface is covered with 100 µl of the test solution. For the water control, drying the dried inoculum on the test surface is covered with 100 µl of the hard water. The test surface is maintained at a specified temperature for a defined period of time, the test surface is transferred to a separate container and 0.9 ml of ice-cold medium is added to a separate container, each container is mixed for 60 s to resuspend the virus. Series of ten-fold dilutions of the virus suspension in ice-cold medium are prepared and the dilutions are inoculated on cell culture. Two surfaces are used for each test. After incubation, the titre infectivity is calculated according to Spearman-Kärber method.

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S62/2019
Rep No: 49
Sample name: **F173**
Sampled: by client
Sampling point: Christeyns France S.A., Vertou
Client: Christeyns France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 11.2.2019
Sample delivered: 13.2.2019
Testing date: 18.7. – 24.7.2019
Delivered amount: 250 ml
Batch No: 181221/0823-01
Page: 3

Preparation of the test

1. Determination of the number of the microorganisms CFU/ml in the product
2. Preparation of cell culture
3. Preparation of the test virus suspension
4. Test of viral infectivity
5. Virus titration with interfering substance
6. Cytotoxicity of the product
7. Reference virus inactivation test
8. Test procedure for virucidal activity of product on carriers

Note:
Virucidal activity – the capability of a product to produce a reduction in the number of infectious virus particles under defined conditions on carriers by at least a 4 lg reduction.

The standard:
EN 16777:2019 Chemical disinfectants and antiseptics – Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area – Test method and requirements (Phase 2/Step 2) December 2018

The Number of CFU in the tested product: 0 CFU/ml

1. Testing the efficacy of chemical disinfectant **F173** on *Vaccinia virus* strain Elstree CAPM V-160

Tab No. 1.1 Table of results of product **F173** on *Vaccinia virus* strain Elstree CAPM V-160

Product	Concentration	Interfering substances	Level of cytoxicity	- $\log_{10}$ $TCID_{50}$ after 5 min	- $\log_{10}$ $TCID_{50}$ after 15 min
F173	0.25%	dirty	3.50 ± 0.00	-	4.09 ± 0.09
F173	0.20%	dirty	-	-	4.59 ± 0.09
F173	0.10%	dirty	-	-	5.09 ± 0.09
Glutardialdehyde	50 ppm	clean	≤2.50 ± 0.00	5.42 ± 0.25	-
			Virus titration, time = 0		
Virus control	-	PBS	-	8.75 ± 0.25	-
Virus control	-	clean	-	8.25 ± 0.09	-
Virus control	-	dirty	-	-	8.42 ± 0.09
Virus control	-	-	9.00	-	9.17

Tab No. 1.2 Testing the efficacy of chemical disinfectant **F173** on *Vaccinia virus* strain Elstree CAPM V-160

Test concentration	Titre of the virus suspension - $\log_{10}$ $TCID_{50}$	Interfering substances	Contact time	- $\log_{10}$ $TCID_{50}$ after test procedure	$\Delta\log_{10}$ $TCID_{50}$
0.25%	8.42 ± 0.09	dirty	15 min	4.09 ± 0.09	**4.33** ± 0.25
0.20%	8.42 ± 0.09	dirty	15 min	4.59 ± 0.09	**3.83** ± 0.25
0.10%	8.42 ± 0.09	dirty	15 min	5.09 ± 0.09	**3.33** ± 0.25

Tab No. 1.3 Testing the efficacy of chemical disinfectant **Glutardialdehyde** on *Vaccinia virus* strain Elstree CAPM V-160

Test concentration	Titre of the virus suspension - $\log_{10}$ $TCID_{50}$	Interfering substances	Contact time	- $\log_{10}$ $TCID_{50}$ after test procedure	$\Delta\log_{10}$ $TCID_{50}$
50 ppm	8.25 ± 0.09	clean	5 min	5.42 ± 0.25	**2.83** ± 0.53

Note: $TCID_{50}$- 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S62/2019
Rep No: 49
Sample name: **F173**
Sampled: by client
Sampling point: Christeyns France S.A., Vertou
Client: Christeyns France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 11.2.2019
Sample delivered: 13.2.2019
Testing date: 18.7. – 24.7.2019
Delivered amount: 250 ml
Batch No: 181221/0823-01

2. Evaluation of virucidal activity of the product **F173**

Tab No. 2.1 The efficacy of chemical disinfectant **F173** on test viruses – virucidal activity

Virucidal activity of the product (EN 16777:2018)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]	Interfering substances - conditions	$\Delta\log_{10}$ $TCID_{50}$ EN 16777:2018	$\Delta\log_{10}$ $TCID_{50}$
Vaccinia virus strain Elstree CAPM V-160	20	15	0.25%	dirty	≥ 4	**> 4**
Vaccinia virus strain Elstree CAPM V-160	20	15	0.20%	dirty	≥ 4	**< 4**
Vaccinia virus strain Elstree CAPM V-160	20	15	0.10%	dirty	≥ 4	**< 4**

Tab No. 2.2 The efficacy of chemical disinfectant **Glutardialdehyde** on test viruses – virucidal activity

Virucidal activity of the product (EN 16777:2018)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	$\Delta\log_{10}$ $TCID_{50}$ EN 16777:2018	$\Delta\log_{10}$ $TCID_{50}$
Vaccinia virus strain Elstree CAPM V-160	20	5	50 ppm	clean	<3.0	**2.83**

Note: $TCID_{50}$- 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

Prepared by: Bc. Iva Čížová, Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S62/2019
Rep No: 49
Sample name: **F173**
Sampled: by client
Sampling point: Christeyns France S.A., Vertou
Client: Christeyns France S.A., 31, Rue de la Maladrie, Vertou

Sampling date: 11.2.2019
Sample delivered: 13.2.2019
Testing date: 18.7. – 24.7.2019
Delivered amount: 250 ml
Batch No: 181221/0823-01
Page: 5

Interpretation:
Results of tests are in Tabs.
According to EN 16777:2018 the tested product **F173**, batch No. 181221/0823-01, in the concentration 0.25%, diluted in hard water, and in the contact time 15 min under dirty conditions at temperature 18 °C ± 1 °C to 25 °C ± 1 °C on carriers **proved** by the method of virus titration on monolayers of cells on microtitre plates to reduce the number of infectious *Vaccinia virus* strain Elstree CAPM V-160 particles under defined conditions by at least a 4 lg reduction.

Conclusion:
The product **F173** is capable of reducing the number of infectious *Vaccinia virus* on carriers under defined conditions (EN 16777:2018 - 0.25%, 15 min, dirty, 18° C – 25°C) to the declared values, and consequently, can be called virucidal on enveloped viruses.

Chemila, spol. s r.o. -2-
Za Dráhou 4386/3, 695 01 Hodonín
tel.: 518 340 919
IČ: 25304518, DIČ: CZ25304518

31.10.2019, Hodonín

.....
Ing. Barbora Stoklásková, Leader of Study

Raw data EN 16777 – product **F173** tested against *Vaccinia virus* strain Elstree CAPM V-160
Sample S62/2019, the test report S62-2/2019,
period of analysis: 18.7. – 24.7.2019
EN 16777: *Vaccinia virus* strain Elstree CAPM V-160 - 3rd passage (VÚVL Brno, 13.1.2011),
VERO cells – Vero, Kidney, African Green Monkey, ATCC-CCL-81 – 19th passage (LGC Standards Sp. z o.o., PL, 25.1. 2019)

Product diluent: hard water
Appearance of the product: colourless liquid
The test concentration: 0.25%, 0.2%, 0.1%
Contact time: 15 min
Interfering substances: 3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)
Reference product: Glutaraldehyde (50% solution in water) for synthesis, CAS: 111-30-8, Batch No: S7460593, minimum shelf life 31.01.2021, date of delivery: 6.3.2019 (50 ppm, 5 min, clean conditions)
The drying time: 25 min

Product	Concentration	Interfering substance	Contact time min	Dilution (lg)[a]								
				carrier	3	4	5	6	7	8	9	10
F173	0.25%	dirty	15	1	444 444	222 200	000 000	000 000	000 000	000 000	000 000	000 000
				2	444 444	200 202	000 000	000 000	000 000	000 000	000 000	000 000
F173	0.20%	dirty	15	1	444 444	222 222	000 000	000 000	000 000	000 000	000 000	000 000
				2	444 444	222 222	200 000	000 000	000 000	000 000	000 000	000 000
F173	0.10%	dirty	15	1	444 444	222 222	202 220	000 000	000 000	000 000	000 000	000 000
				2	444 444	222 222	200 202	000 000	000 000	000 000	000 000	000 000
Glutardialdehyde	50 ppm	clean	5	1	344 333	333 333	222 020	000 000	000 000	000 000	000 000	000 000
				2	344 333	333 333	222 222	200 000	000 000	000 000	000 000	000 000
Virus control	n.a.	PBS	5	1	444 444	444 444	333 333	333 333	222 222	222 222	000 000	000 000
				2	444 444	444 444	333 333	333 333	222 222	222 222	220 002	000 000
Virus control	n.a.	clean	5	1	444 444	444 444	333 333	333 333	222 322	220 222	000 000	000 000
				2	444 444	444 444	333 333	333 333	222 222	220 220	000 000	000 000
Virus control	n.a.	dirty	15	1	444 444	444 444	333 333	333 333	322 222	222 222	000 000	000 000
				2	444 444	444 444	333 333	333 333	232 232	222 220	000 000	000 000
F173 Cytotoxicity	0.25%	clean	n.a. n.a.	1	444 444	000 000	000 000	000 000	n.d.	n.d.	n.d.	n.d.
				2	444 444	000 000	000 000	000 000	n.d.	n.d.	n.d.	n.d.
Glutardialdehyde **cytotoxicity**	50 ppm	clean	5	1	000 000	000 000	000 000	000 000	n.d.	n.d.	n.d.	n.d.
				2	000 000	000 000	000 000	000 000	n.d.	n.d.	n.d.	n.d.
Interference control	non-cytotoxic concentration	n.a.	n.a.	n.a.	444 444	444 444	333 333	333 333	222 222	222 000	220 200	000 000
Neutralization	0.25%	dirty	n.a.	n.d.	n.d.	444 444	333 333	333 333	222 222	222 222	n.d.	n.d.
Virus control	n.a.	-	0	n.a.	444 444	444 444	333 333	333 333	222 222	222 222	000 000	000 000
			15	n.a.	444 444	444 444	333 333	333 333	222 222	222 222	020 000	000 000

a – dilution
1 to 4 – degree of CPE in 6 cell culture units
0 – no CPE
n.a. – not applicable
n.d. – not done
$TCID_{50}$- 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

Prepared by: Bc. Iva Čížová, Lab Technician
Controlled by: Ing. Barbora Stoklásková, Leader of Study