vileda PROFESSIONAL
a brand of FREUDENBERG

Micro Control
無菌/無塵清潔系統
Product Information

澤和科技股份有限公司 | 台北總公司：台北市內湖區新湖二路19號2樓 | www.tsetech.com.tw
無塵衣工廠：(一廠) 中國江苏省昆山市周市镇渔业新村28号 (二廠) 中國江苏省塩城市建湖縣垛口鎮育才路1号
無塵鞋工廠：台中市神岡區社南街 | 服務專線：02-27955856 | 傳真：02-27955756 | E-mail:sales@tsetech.com.tw

vileda PROFESSIONAL
a brand of FREUDENBERG

德國製造

Micro Control 無塵拖把

無菌/潔淨室清潔 盡在掌握

- 適用於Gamma射線和高溫高壓滅菌，且高度耐化學腐蝕
- 可重複清洗200次以上 or 重複清洗加滅菌消毒至少80次以上
- 第三方的測試報告證實，可有效去除99.9%的表面微粒(Bacteria)
- 專利拖把頭 " 凸緣 " 設計，可有效清潔牆角/桌腳...附近

GMP A/B 區域 - 高效清潔預浸漬系統 (避免交叉汙染可能性)

Swep Duo Plus Frame

雙面拖把頭，可濕熱滅菌。
特殊拉把設計，更換拖把布零污染。

137878 ． 50cm ． 1箱 / 10支

MicroControl mop

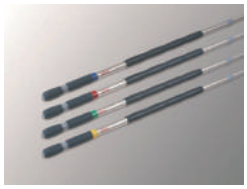
超細纖維拖把替換拖把布
可重複洗滌200次，濕熱滅菌80次以上。
配合”預浸漬”清潔方式，可完全避免交叉污染並大量節省消毒劑使用成本。
測試實證，乾擦即可去除99.9%的表面微粒。

140708 ． 50cm ． 1箱 / 30片

Origo Bucket

6公升預浸漬桶 + 蓋
高品質聚丙烯材質，可濕熱滅菌。
附四色分區卡，輕鬆辨別所對應區域，
一次可預浸漬 4 - 5片的替換拖把布。

120942 ． 6公升準備桶 ． 1箱 / 10個
125948 ． 6公升桶蓋 ． 1箱 / 12個



Telescopic handle

伸縮拖把桿
可伸縮範圍100~180cm，可濕熱滅菌。
附四色分區環，輕鬆辨別所對應的區域。

119966 ． 100-180cm(可伸縮) ． 1箱 / 10支

Origo Sieve

預浸漬篩子
可濕熱滅菌。
使清潔劑與消毒水均勻浸潤每片替換頭。

120779 ． 1箱 / 3個

Origo Box

15公升預浸漬桶 + 蓋
高品質聚丙烯材質，可濕熱滅菌。
附四色分區卡，輕鬆辨別所對應區域，
一次可預浸漬 10 - 12片的替換拖把布。

120774 ． 15公升準備桶 ． 1箱 / 5個
120780 ． 15公升桶蓋 ． 1箱 / 5個

GMP C/D 區域 / 無塵室區域

UltraSpeed Pro frame

超高速拖把頭
搭配超高速擠壓器和超高速拖把替換拖把布使用。

146963 ． 40cm ． 1箱 / 10支

1.

UltraSpeed ProDouble Bucket Starter Kit Push

2.

超高速雙桶清潔套裝
配件皆可做更換，可大幅降低使用者成本。
內含：25公升桶 x1 , 8公升桶 x1 , 拖把頭 x1
替換拖把布 x 1 , 擠壓器 x 1 , 四輪底座 x 1
推車把手 x 1 (不含伸縮拖把桿)

147206 ． 1箱 / 1套

Telescopic handle

伸縮拖把桿
可伸縮範圍100~180cm，可濕熱滅菌。
附四色分區環，輕鬆辨別所對應的區域。

119966 ． 100-180cm(可伸縮) ． 1箱 / 10支

3.

4.

UltraSpeed mop

超高速拖把替換布
帶有四色分區標示織帶，可輕易區分使用區域，耐洗程度超過200次，且具有通過GMP C級區的顆粒釋放測試報告。

143222 ． 40cm ． 1箱 / 20片

1.

2.

3.

4.

澤和科技股份有限公司
地址：台北市內湖區新湖二路19號2樓
服務信箱：sales@tsetech.com.tw
聯絡電話：02-2795-5856
www.tsetech.com.tw

TECHNICAL DATA SHEET

Telescopic Handle, long

1. INTERNATIONAL ARTICLE NUMBER:
119966 (blue, red, yellow, green clip)

2. PRODUCT CLASSIFICATION:
Telescopic Handle 100 – 180 cm

3. COMPOSITION:

- Plastic parts: Top grip area: Thermo Plastic Elastomer
  Glossy mid grey areas: Polypropylene
  Mid grip: Polypropylene
- Tubes: Welded Aluminium tube, lower end outside Ø 22 mm, inside Ø 20 mm

4. TECHNICAL DATA:

	Typical Value	Unit
Weight Telescopic handle 100-180 cm	465	g

5. PRODUCT PROPERTIES & PRODUCT USAGE

- Long Top grip (18,5 cm): ergonomic shape with rounded end, soft grip areas incl. anti slip function
- Extra long mid grip (40 cm): ergonomic shape with multi hand positions
- Improved locking mechanism
- Light weight
- To be used with all Swep frames, Multi Squeegee, CombiSpeed Frame, Padmaster
- Suitable for autoclaving

6. STORAGE, TRANSPORTATION & DISPOSAL
Keep palletized products in a cold and dry place. Avoid exposure to direct sunlight. Product is not subject to transportation regulations for hazardous substances or chemicals. Disposal via landfill or incineration possible.

7. QUALITY APPROVALS / COMPLIANCE WITH INTERNATIONAL STANDARDS
This product is manufactured conforming to appropriate standards within FHP Quality System.

Date: 2007/03/22

Freudenberg Haushaltsprodukte KG
Corporate Technical Centre,
Höhnerweg 2 – 4, Bau 148
D – 69465 Weinheim

Telefon: +49 (0) 6201 80 - 4336
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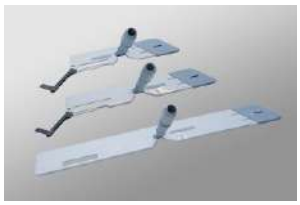
Swep Duo & Swep Duo Plus Frame



1. INTERNATIONAL ARTICLE NUMBER:
143062 (35 cm, Swep Duo Plus frame)
137878 (50 cm, Swep Duo Plus frame)
116868 (75 cm, Swep Duo frame)

2. PRODUCT CLASSIFICATION:
Plastic frame for Swep Single and Swep Duo mops

3. COMPOSITION:
- Plastic parts: Polypropylene
  Polyamide
  Thermoplastic elastomers
  Polyoxymethylene
- Metal parts: Stainless steel
  Brass, nickel-plated

4. TECHNICAL DATA:

	Typical Value	Unit
Weight 35 cm frame	217	g
Weight 50 cm frame	295	g
Weight 75 cm frame	470	g

5. PRODUCT PROPERTIES & PRODUCT USAGE
- To be used one sided with all Swep Single mops or two sided with all Swep Duo mops
- For two sided mopping, frame is just flipped on the other side
- Easy to put mop on the frame due to gripping hole and spring-supported mop mounting
- With lever and built-in finger-tag in order to ensure a hygienic mop release from the frame without need to touch the mop (Swep Duo Plus frame)
- Sticker with arrow to indicate working direction
- Flexible connection element for even pressure from the center and out.
- Possibility to work front-wards and backwards
- Ergonomic working due to lightweight construction
- Trapezoid shape to ensure good dirt removal in corners
- Thin frame to reach under narrow areas
- For floor, side walls and ceiling cleaning
- Autoclavable at 121°C

6. STORAGE, TRANSPORTATION & DISPOSAL
Keep palletized products in a cold and dry place. Avoid exposure to direct sunlight. Product is not subject to transportation regulations for hazardous substances or chemicals. Disposal via landfill or incineration possible.

7. QUALITY APPROVALS / COMPLIANCE WITH INTERNATIONAL STANDARDS
This product is manufactured conforming to appropriate standards within FHCS Quality System.

Date: 2015/08/14

FREUDENBERG HOME AND CLEANING SOLUTIONS GMBH

Regional Technical Centre Europe
Höhnerweg 2 -4, Bau 149
69469 Weinheim, Germany

E-Mail: vileda.professional@fhp-ww.com
www.vileda-professional.com

Telefon: +49 (0) 6201 80 - 4336
Fax: +49 (0) 601 88 - 4339

Technical Data Sheet

MicroControl Mop CC

International Article Number

151327 (50 cm)

Product classification

Microfibre mop

Composition

Backing (white):	100 %	Polyester
Inner layer:	100 %	Polyester
Fabric (blue):	100 %	Polyester Microfibre

Technical data

	Typical value	Unit
Weight	128	g
Max. water absorption	250	mL

Product properties and product usage

- Application areas: Controlled Environment cleaning of floor, wall and ceiling
- Heat- and chemical resistant
- Suitable for gamma and autoclave sterilization
- Designed for use in cleanroom class ISO 5 / GMP A+B / FED209 D class 100
- Mop preparation: 220 mL per 50 cm mop

Washing recommendation:

- Ideal conditions: 60°C, avoid high alkalinity and strong bleaching activity (do not use chlorine bleach); tumble dry at low heat
- Maximum washing temperature: 95°C

Storage, transportation and disposal

Keep palletized products in a cold and dry place. Avoid exposure to direct sunlight. Product is not subject to transportation regulations for hazardous substances or chemicals. Disposal via landfill or incineration possible.

Quality approvals / Compliance with international standards

This product is manufactured conforming to appropriate standards within FHCS Quality System.

Date: 2016/03/14

Vileda Professional
Freudenberg Home and Cleaning Solutions, Im Technologiepark 19, D – 69469 Weinheim
Phone 1234567890, Fay 1234567890, e-mail: vileda.professional@fhp-ww.com, www.vileda-professional.com

TECHNICAL DATA SHEET

6L bucket

1. INTERNATIONAL ARTICLE NUMBER:
120942

2. PRODUCT CLASSIFICATION:
Bucket, 6L

3. COMPOSITION:

Body:	100	%	Polypropylene
Bail:	100	%	Stainless steel

4. TECHNICAL DATA:

	Typical Value	Unit
Width	28	cm
Depth	18	cm
Height	21	cm
Weight	575	g

5. PRODUCT PROPERTIES & PRODUCT USAGE

- Fits on the Origo trolley system
- Suitable for Cleanroom cleaning
- With stainless steel bail
- Fully autoclavable
- Colour coding clips offer simple identification of different application areas

6. STORAGE, TRANSPORTATION & DISPOSAL
Keep palletized products in a cold and dry place. Avoid exposure to direct sunlight. Product is not subject to transportation regulations for hazardous substances or chemicals. Disposal via landfill or incineration possible.

7. QUALITY APPROVALS / COMPLIANCE WITH INTERNATIONAL STANDARDS
This product is manufactured conforming to appropriate standards within FHP Quality System.

Date: 2011/01/27

Freudenberg Haushaltsprodukte KG
Regional Technical Centre Europe
Höhnerweg 2 – 4, Bau 148
D – 69465 Weinheim

Telefon: +49 (0) 6201 80 - 4336
Fax: +49 (0) 6201 88 - 4339

Autoclave Test Report

PRODUCT

Telescopic Handle

Composition

Top grip area:	Thermo Plastic Elastomer
Glossy mid grey areas:	Polypropylene
Mid grip:	Polypropylene
Welded aluminium tube	

TEST CONDITIONS

Autoclave
Varioklav 135 S, steam sterilizer, single pre-vacuum, usable volume 135 litres

Test Parameters
121°C for 20 minutes
Pre-vacuum: 20 kPa
Cooling-down of product between autoclaving cycles

RESULT

After 80 autoclaving cycles the Telescopic Handle does not show major damages and is still usable. Just the lower grip of the long telescopic handle could get out of position and the inner screw becomes a bit loosen.

Photo 1: Telescopic Handle frame after 80 cycles

Photo 2: Inner screw becomes a bit loosen

ADDITIONAL COMMENTS

- This test was done in the laboratory of Freudenberg HP KG, Corporate Technical Centre.
- The product was not used for cleaning between autoclaving cycles.
- Different conditions at the customer can lead to a different result.

Date: 2007/10/11

Freudenberg Haushaltsprodukte KG
Corporate Technical Centre,
Höhnerweg 2 – 4, Bau 148
D – 69465 Weinheim

Telefon: +49 (0) 6201 80 - 4336
Fax: +49 (0) 6201 88 - 4339

Autoclave Test Report

PRODUCT

Swep Duo Plus frame

International Article Number:
137878 (50 cm)

Composition

- Plastic parts : Polypropylene, Polyamide, Thermoplastic elastomers, Polyoxymethylene
- Metal parts : Stainless steel, Brass (nickel-plated)

TEST CONDITIONS

Autoclave
Varioklav 135 S, steam sterilizer, single pre-vacuum, usable volume 135 litres

Test Parameter
121°C for 20 minutes
Pre-vacuum: 20 kPa
Cooling-down of product between autoclaving cycles

RESULT
After 80 autoclaving cycles the Swep Duo Plus does not show any damages and fulfills FHP specification requirements. The frame shows a light deformation when not placed horizontally in the autoclave.

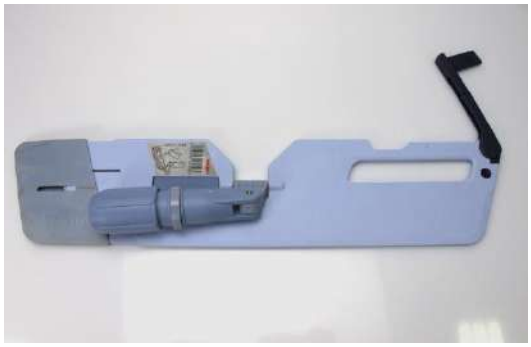


Photo: Swep Duo Plus frame after 80 cycles

ADDITIONAL COMMENTS

- This test was done in the laboratory of FHP SE & Co.KG, Regional Technical Centre.
- The product was not used for cleaning between autoclaving cycles.
- Different conditions at the customer can lead to a different result.

Date: 2012/10/15

Freudenberg Haushaltsprodukte SE & Co.KG
Regional Technical Centre,
Höhnerweg 2 – 4, Bau 148
D – 69465 Weinheim

Telefon: +49 (0) 6201 80 - 4336
Fax: +49 (0) 6201 88 - 4339

Autoclave Test Report

PRODUCT

MicroControl Mop

Composition

Cleaning side:	100	%	Polyester Microfiber
Inner core:	100	%	Polyester
Backing:	100	%	Polyester

TEST CONDITIONS

Autoclave

Varioklav 135 S, steam sterilizer, single pre-vacuum, usable volume 135 litres

Test Parameter

121°C for 20 minutes
Pre-vacuum: 20 kPa
Cooling-down of product between autoclaving cycles

RESULT

After 80 autoclaving cycles the MicroControl Mop does not show any damages and fulfills FHP specification requirements. Only the white backing partially shows discoloring.

Photo 1: MicroControl Mop after 80 autoclaving cycles

ADDITIONAL COMMENTS

- This test was done in the laboratory of Freudenberg HP KG, Regional Technical Centre.
- The product was not used for cleaning between autoclaving cycles.
- Different conditions at the customer can lead to a different result.

Date: 2012/08/22

Freudenberg Haushaltsprodukte KG
Regional Technical Centre Europe
Höhnerweg 2 – 4, Bau 148
D – 69465 Weinheim

Telefon: +49 (0) 6201 80 - 4336
Fax: +49 (0) 6201 88 - 4339

Autoclave Test Report

PRODUCT

25L Bucket long & 6L Bucket, stainless steel bail
TSU:131662 (25L bucket long), 120942 (6L bucket)

Composition
Body: 100 % Polypropylene
Bail: 100 % Stainless Steel

TEST CONDITIONS

Autoclave
Varioklav 135 S, steam sterilizer, single pre-vacuum, usable volume 135 litres

Test Parameter
121°C for 20 minutes
Pre-vacuum: 20 kPa
Cooling-down of product between autoclaving cycles

RESULT
After 80 autoclaving cycles both buckets do not show any damages and fulfills FHP specification requirements.

Photo 1: Bucket 6L (top view) after 80 autoclaving cycles

Photo 2: 25L (side view) after 80 autoclaving cycles

ADDITIONAL COMMENTS
- This test was done in the laboratory of Freudenberg HP KG, Regional Technical Centre.
- The product was not used for cleaning between autoclaving cycles.
- Different conditions at the customer can lead to a different result.

Date: 2011/09/22

Freudenberg Haushaltsprodukte KG
Regional Technical Centre.
Telefon: +49 (0) 6201 80 - 4336
Fax: +49 (0) 6201 88 - 4339

Wash Test Report

TESTED PRODUCT
MicroControl mop

Composition

Backing (white):	100 % Polyester
Inner layer:	100 % Polyester
Fabric (blue):	100 % Polyester Microfibre

TEST CONDITIONS

Washing Machine:
Miele PW 6101FT Profitronic M, capacity: 10 kg, max g-factor: 475

Washing Detergent:
- Type: powder for chemo-thermal disinfection, producer: Ecolab, product: Eltra (German version)
- Concentration: 7g/L (210g/load)
- PH-value of wash liquor: 10.5

Washing Program:
- Loading: 6kg +/-1kg
- Pre-washing: cold water without washing detergent, 1 time washing/in-between spinning
- Main washing: temperature 60°C
- Rinsing: cold water, 3 times washing /in-between spinning

RESULT
After **200 washing cycles** the MicroControl mop does not show any damages and fulfils FHP specification requirements.

Photo 1: Mop after 200 washing cycles – back side
Photo 2: Mop after 200 washing cycles - front side

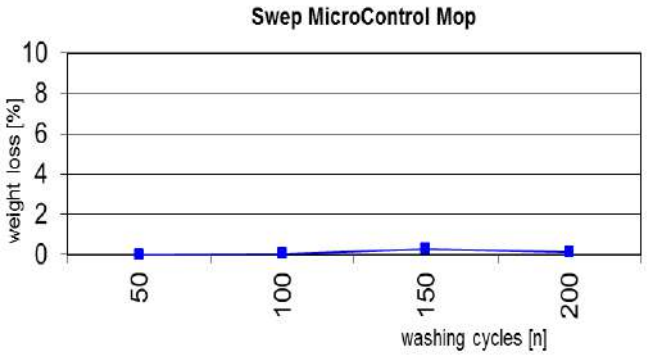


Diagram: MicroControl mop - weight loss in %

ADDITIONAL COMMENTS
- This test was done in the laboratory of Freudenberg Haushaltsprodukte KG, Technical Centre Europe.
- The product was not dried in between wash cycles and was not used for cleaning.
- The results of the test above are to be used as a guideline and not a guarantee. In real life conditions the results can be lower (e.g. if washed at a higher temperature) or higher (e.g. if a mild washing detergent for coloured textiles is used).

Date: 2012/09/06

Freudenberg Haushaltsprodukte SE & Co. KG
Regional Technical Centre Europe
Höhnerweg 2 – 4, Bau 148
D – 69465 Weinheim

Telefon: +49 (0) 6201 80 - 4336
Fax: +49 (0) 6201 88 - 4339

Laboratory Report

Client:	Freudenberg Haushaltsprodukte KG, Technical Centre Europe Bau 149 Hoehnerweg 2-4, 69469 Weinheim Herr Jörg Dunkel		
Your date of order:	25.04.2012	Receipt of samples / sampling:	30.04.2012
Your order no.:		Period of analysis:	10.-24.05.2012
BMA order no.:	AU120425-05	Date of report:	08.06.2012
BMA sample no.:	120430-06/3	Report no.:	BE120425-05/3
Report writing:	U. Stephan		Page 1 of 2

Sample

Cloth: ***Vileda Professional MicroControl Mop M*** (The sample was sent by the customer)

Analyses

Microbiological examination of products
Evaluation of the capability of the cloth Vileda Professional MicroControl Mop M to reduce bacteria on floor surfaces

1. Method(s) and material

The present study is based on EN 1174-2, DIN EN ISO 846, method C the customer's instructions and BMA-Laboratory reports of AU060519-02.
The test was performed in a clean bench.
Bacteria test strain: *Pseudomonas aeruginosa* (DSM-Nr. 288)
Neutral cleaner: Tana Green care Neutral-Reiniger 04631 (TANA Chemie GmbH, Mainz, Germany)
Test surface: PVC floor covering, non structured (89 cm x 27 cm), disinfected; subdivided into 39 sample squares (9 cm x 7 cm)
Samples 3.1 to 3.3: Negative control after disinfection, samples 3.4 to 3.9: Positive control after bacteria application, samples 3.10 to 3.39: treated sample squares after bacteria application and cleaning with the test cloth.

Applied bacteria suspension

5 ml of *P. aeruginosa* suspension (5,3 x 10^{11} cfu (colony forming unit)); amount per test sample (9 cm x 7 cm): 1,2 x 10^{9}.

Eluation and determination of bacteria from the sample squares

Samples were incubated in 15 ml 0,9 % NaCl solution in a falcon tube and shaked 20 min end to end. The bacteria concentration of the suspension was analysed using the spread plate method (100 µl plating volume of dilution series) and/or the filtration method for samples with expected high or low bacteria contamination respectively. The agar plates were cultivated 5 days at 30°C.

Cleaning procedure

The cloth was moistened by spraying 80 ml 1% neutral cleaner in water. Then it was fixed to the cleaning device, wiped once across the test surface by moving it in form of an 8 with a homogenous pressure at a speed of approximately 5 cm/s based on instrutions of the customer.

2. Results

2.1 Amount of aerobic mesophilic bacteria after disinfection

The results of the measurements and analyses exclusively refer to the examined sample(s).

Sample / Sample identification	Sample No.	Sample description	Mean concentration of mesophilic bacteria	
			Sample square (56 cm²) [CFU/15 ml]	[CFU/m²]
Control 120430-06/3	3.1-3.3	Negative control after disinfection	28 [(a)]	5000

[(a)] Detection limit filtration: 1 cfu/15 ml
[(b)] Detection limit spread plate: 150 cfu/15 ml

2.2 Amount of *Pseudomonas aeruginosa* before and after cleaning

The results of the measurements and analyses exclusively refer to the examined sample(s).

Sample / Sample identification	Sample No.	Sample description	Mean concentration of *P. aeruginosa*	
			Sample square (56 cm²) [CFU/15 ml]	[CFU/m²]
Cloth: ***Vileda Professional MicroControl Mop M*** 120430-06/3	3.4-3.9	Positive control after bacteria application	1,0 x 10^9 [(b)]	1,8 x 10^{11}
	3.10-3.39	Treated sample squares after bacteria application and cleaning with the test cloth	32 [(a), (b)]	5714
		Reduction [%]	99,9	

[(a)] Detection limit filtration: 1 cfu/15 ml
[(b)] Detection limit spread plate: 150 cfu/15 ml

Dr. Ute Stephan
Technical Manager

Stephanie Putz
Lab. analysis & organisation

DNV BUSINESS ASSURANCE

MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 51151-2009-AQ-FIN-FINAS

This is to certify that

FREUDENBERG HOUSEHOLD PRODUCTS OY AB

Joensuunkatu 11, 24100 Salo; Finland

has been found to conform to the Management System Standard:

ISO 9001:2008

This Certificate is valid for the following product or service ranges:

Development and manufacture of cleaning systems and devices.

Initial Certification date:
18 September 1995

This Certificate is valid until:
30 April 2018

The audit has been performed under the supervision of
Tom Essén
Lead Auditor

FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

Place and date:
Espoo, 13 April 2015

for the Accredited Unit:
DNV GL BUSINESS ASSURANCE FINLAND OY AB

Kimmo Haarala
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

Certificate

Standard **BS OHSAS 18001:2007**

Certificate Registr. No. 01 213 120485

Certificate Holder:

Freudenberg Haushaltsprodukte Augsburg GmbH
Provinostr. 52
D - 86153 Augsburg

Scope: Development, production and distribution of household products for private and commercial applications

Proof has been furnished by means of an audit that the requirements of BS OHSAS 18001:2007 are met.

Validity: The certificate is valid from 2015-05-24 until 2018-05-23.

First certification 2004

2015-06-02

LGA InterCert GmbH
Tillystr. 2 · 90431 Nürnberg

www.lga-intercert.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16039-01-00

LGA InterCert Zertifizierungsgesellschaft mbH

10/209 10.12 A4

Freudenberg Home and Cleaning Solutions GmbH
Höhnerweg 2-4 Bau 149 Phone +49 6201 80 4336
69469 Weinheim Fax +49 6201 88 4339

EC DECLARATION OF CONFORMITY

CAT. III

The manufacturer, established in the European Community:

Freudenberg Home and Cleaning Solutions GmbH
Im Technologiepark 19
D-69469 Weinheim - GERMANY

declares that the PPE described hereafter:

UNIVERSAL

2001X
EN 388

KOS
EN ISO 374-1/Type B EN ISO 374-5

is in conformity with the provisions of Article 10 of the Council Directive **89/686/EEC** and with the European standards **EN 420:2003+A1:2009, EN 388:2016, EN ISO 374:2016** and is identical to the PPE which is subject to the EC Type Examination certificate number **049/2017/1105** issued by the Notified Body:

CENTEXBEL
TECHNOLOGIEPARK 7
B-9052 ZWIJNAARDE

and is subject to the procedure set out in Article 11 point B of Directive **89/686/EEC** under the supervision of the Notified Body :

BSI (0086)
Kitemark Court Davy Avenue Knowlhill
Milton Keynes MK5 8PP United Kingdom

Dr. Julia von Grote-Pastré
R&D Manager
Freudenberg Home and Cleaning Solutions GmbH

December, 7th, 2017

Bayer Pharma AG 11/14/17

10903 New Hampshire Avenue
Silver Spring, MD 20993

Via UPS

Warning Letter 320-18-08

November 14, 2017

Werner Baumann
Chief Executive Officer
Bayer AG
Kaiser-Willhelm-Allee
Building W11
51368 Leverkusen
Germany

Dear Mr. Baumann:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Bayer Pharma AG at Kaiser-Willhelm-Allee, Building W11, Leverkusen, from January 12–20, 2017.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 CFR, parts 210 and 211.

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We reviewed your February 10, 2017, response in detail and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigators observed specific violations including, but not limited to, the following.

1. Your firm failed to establish and follow adequate written procedures for cleaning and maintenance of equipment (21 CFR 211.67(b)).

Your equipment cleaning practices for non-dedicated equipment are inadequate.Your firm has several (b)(4) that can be used for more than one product.

A. *Equipment exterior surfaces*
During the production of your drug product (b)(4), which was in a (b)(4), our investigator observed a (b)(4) residue on the (b)(4) exterior surfaces. Your manufacturing area personnel stated that the residue was probably from a (b)(4) drug product, (b)(4), which was previously processed in the same room.

After our inspection, you tested samples of tablets produced with (b)(4) manufactured in the same (b)(4) to assess the potential for cross-contamination. Your testing confirmed the presence of (b)(4) in (b)(4) tablets, which you had produced as a contract manufacturer for your customer, (b)(4). (b)(4) recalled several lots of (b)(4) on (b)(4), due to the cross-contamination problem.

B. (b)(4) *on manufacturing equipment*
In three different rooms, our investigator observed white residues in and around the (b)(4) of three (b)(4) identified as "clean." Your cleaning procedure did not include provisions for cleaning (b)(4) in (b)(4).

Residues in and around (b)(4) can lead to the ingress of cross-contaminants into manufacturing equipment.

In your response, you committed to a number of corrective actions and preventive actions (CAPA) for (b)(4), including reevaluating cleaning procedures and practices, assessing the effect of residues on quality and safety of products, and retraining personnel involved with cleaning.

Your response was inadequate. You did not sufficiently assess whether U.S.-shipped products manufactured with the (b)(4) were cross-contaminated.Additionally, you did not reevaluate your cleaning procedures, practices, and validation for other non-dedicated manufacturing equipment.

In response to this letter, provide:

- Your retrospective review supporting the safety and purity of each batch of product manufactured with your (b)(4) that remain within expiry in the U.S. market. Include a summary report of analytical testing results supporting your conclusions. Provide scientific justification if you to propose to exclude any batch that remains within expiry from this retrospective testing.
- A comprehensive plan to assess cleaning procedures, practices, and validations for each piece of manufacturing equipment used to manufacture more than one product. Also include your plans to ensure that powder residues are removed from room surfaces as part of product changeovers.

2. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

Your investigations into product quality complaints are inadequate. For example, when you investigated two complaints of leaking (b)(4) containing (b)(4) batch (b)(4), you did not determine a root cause for the container-closure defect. Your (b)(4) supplier informed you of a (b)(4) defect that you did not address in your investigation. The investigation also failed to include an examination of retain samples or review past complaints to identify other instances of bag integrity defects.

Your response was inadequate because it lacked sufficient improvements to your investigation systems.

In response to this letter, provide:

- A list of all complaints received from 2014 to present that indicate potential bag non-integrity, with detailed descriptions including complaint dates, product names, batch numbers, description of complaint, exact breach

locations, root causes, and CAPA. Include your final, updated investigations into the (b)(4) issues observed in batches (b)(4) and (b)(4).

- A retrospective review of all investigations relating to complaints that could impact the quality of products within expiry in the U.S. market. Include an assessment of the depth of investigation, identification of potential root causes, review of related trends, and CAPA.
- A full assessment and remediation of your systems for investigating complaints, failures, and deviations to ensure they are thorough, scientifically sound, and culminate in appropriate and effective CAPA.
- Procedures requiring more thorough examination or testing of retention samples during investigations, including both the complaint batch and other potentially affected batches
- Procedures that ensure each complaint of a critical defect is carefully evaluated to determine whether marketed products may be impacted. Currently, a problem appears to be escalated only after three complaints are received for a batch.
- Improvements in your ongoing monitoring of vendor or contractor acceptability. Explain how you will ensure that vendors notify you about significant deviations or potential defects in materials (e.g., by modifying quality agreements).

3. Your firm failed to establish an adequate quality control unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling, and drug products, and that approves or rejects all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product (21 CFR 211.22(a) and (c)).

Your quality control unit did not sufficiently oversee adequacy of procedures at your facility to assure drug product quality.

A. *Discarded training records*
Our investigators observed discarded original personnel training records. Your procedure 3-040-127, *Use of the Schulungsdatenbank (Learning Management System) in the Supply Center Leverkusen* requires these records to be maintained. In your response, you committed to retain original training records. However, you did not reassess your program to ensure that personnel were trained and capable of performing their assigned functions.

B. *Discarded automated visual inspection machine parameters*
In a (b)(4) department office waste bin, our investigators observed discarded forms used to document and set inspection parameters for your automated tablet visual inspection machinery. These parameters are used to accept or reject tablets. In your response, you noted that you documented and approved final set-up parameters, “but historically the calculations generated in support of those parameters have not been preserved.” You indicate that programming the visual inspection machine to detect defects may not be a CGMP activity. We note that the parameters of this machinery are used to discriminate between acceptable and unacceptable tablets. Accordingly, entering reliable settings into machine programming is part of CGMP.

In response to this letter:

- Reassess any systems or activities associated with drug manufacturing or testing equipment that you consider “non-GMP.” Provide your reassessment and describe improvements in your procedures for document handling, retention, and destruction.
- Review your training program’s effectiveness, including but not limited to evaluating the reason(s) that some individuals failed to follow standard operating procedures. Summarize your CAPA.

4. Your firm failed to ensure that laboratory records included complete data derived from all tests necessary to assure compliance with established specifications and standards (21 CFR 211.194(a)).

When reviewing audit trails, our investigator observed unreported data from in-process tablet weight checks. You programmed your in-process weight checker not to report values that varied more than (b)(4)% from the tablet

target weight.

In your response, you committed to suspend this procedure, investigate any such values, and perform a retrospective assessment of tablet weight checker data. However, your retrospective tablet weight assessment was limited to all rejected measurements from February 1 to March 15, 2017, and about 8,000 rejected measurements representing an unspecified percentage of the total number of rejected measurements from August 1, 2016, to February 1, 2017. There was no commitment to revisit equipment qualification(s) and process validation(s) to ensure they included complete data.

In response to this letter, as part of your retrospective tablet weight assessment, explain whether your findings impact data supporting tablet manufacturing equipment qualification and manufacturing process validation studies. Provide a summary listing of equipment qualification and process validation documents that you reviewed.

Data Integrity Remediation

FDA acknowledges that, before our inspection, you began a data integrity remediation program. Our investigator documented that, as part of your data integrity remediation program, you discontinued the practice of performing "test" injections as a result of an internal assessment in June 2016. However, we noted that you only reviewed chromatographic data for (b)(4) and (b)(4) generated between January 1, 2015, and June 23, 2016.

Your action plans submitted on May 11, 2017, and August 10, 2017, did not include an assessment of other products manufactured and tested at your facility. Additionally, the retrospective review did not include data generated before January 1, 2015, used in support of drug applications submitted to FDA. Further, your retrospective review only focused on the laboratory. You did not investigate potential data integrity lapses in other manufacturing systems.

In response to this letter, provide your revised action plan. In your summary report, include other products manufactured and tested at your facility and identify any data generated before January 1, 2015, that was used to support drug applications submitted to FDA. Also, include your protocol and methodology. Summarize all laboratories, manufacturing operations, and systems covered by the assessment. Specify whether a qualified independent consultant performed interviews to ensure that the nature and scope of the problem was fully determined. Discuss the role of the independent consultant in auditing the integrity of your data and assisting with CAPA. Justify why you excluded any part of your operations or systems.

Conclusion

Violations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these violations, for determining the causes, for preventing their recurrence, and for preventing other violations in all your facilities.

If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov (mailto:drugshortages@fda.hhs.gov), so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture under 21 U.S.C. 356C(b) and allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

Until you correct all violations completely and we confirm your compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as a drug manufacturer.

Failure to correct these violations may also result in FDA refusing admission of articles manufactured at Bayer Pharma AG at Kaiser-Willhelm-Allee, Building W11, 51368 Leverkusen into the United States under section 801(a)

(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov (mailto:CDER-OC-OMQ-Communications@fda.hhs.gov) or mail your reply to:

Jason F. Chancey
Consumer Safety Officer
U.S. Food and Drug Administration
White Oak Building 51, Room 4359
10903 New Hampshire Avenue
Silver Spring, MD 20993
USA

Please identify your response with FEI 3002806462.

Sincerely,
/S/
Francis Godwin
Acting Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

More in 2017
(/ICECI/EnforcementActions/WarningLetters/2017/default.htm)