SGS INSTITUT FRESENIUS

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Consumer and Retail
Non Food

Taunusstein, 07/04/2017

Prüfbericht Nr. / Test-report no**. 3310995-01**

Prüfbericht-Version / Test-report version **< 2 >**

Dieser Bericht ersetzt Prüfbericht 3310995-01 Version <1> vom 30/03/2017 / This test report replaces test report 3310995-01 version <1> of 30/03/2017

Original Probe Nr. / Original Sample ID	**Probenbeschreibung** / Sample Description	**Probeneingang** / Sample Receipt Date
170239984	multiFlon® ePTFE Dichtungsplatte / gasket sheet 3 mm	06/03/2017

3310995

Allgemeine Angaben / General Information

SGS-Kundennr. / SGS-Client´s ID	:	10156588
SGS-Kundenauftrag / SGS-Customer-Order	:	4085499
Auftragserteilung / Ordering date	:	03/03/2017
Prüfzeitraum / Testing period	:	09/03/2017 – 20/03/2017
Bestell-Nr. / Order No.	:	-
Artikel-Nr. / Item No.	:	151151530
Prüfumfang / Testing scope	:	Prüfung nach Prüfvorschlag Test according to test suggestion

Beurteilung / Assessment

Prüfanforderungen / **Overall assessment**	**bestanden / pass**
In den Untersuchungspunkten entspricht die Probe den Maßgaben des LFGB sowie der Verordnung (EG) Nr. 1935/2004. The sample meets the requirements of LFGB and Regulation (EC) No. 1935/2004 in the tested items.	

SGS INSTITUT FRESENIUS GmbH

i. A. Zamien Sarkardeh
(Project Manager)

i. A. Claas Isemer
(Project Manager)

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Member of the SGS Group (Société Générale de Surveillance)

Die Prüfergebnisse beziehen sich auf die untersuchten Proben. Die Veröffentlichung und Vervielfältigung unserer Prüfberichte und Gutachten zu Werbezwecken sowie deren auszugsweise Verwendung in sonstigen Fällen bedürfen unserer schriftlichen Genehmigung. Alle Dienstleistungen werden auf Grundlage der anwendbaren Allgemeinen Geschäftsbedingungen der SGS, die auf Anfrage zur Verfügung gestellt werden, erbracht.

Geschäftsführer: Stefan Steinhardt, Aufsichtsratvorsitzender: Dirk Hellemans, Sitz der Gesellschaft: Taunusstein, HRB 21543 Amtsgericht Wiesbaden

Zusammenfassung der Analysenergebnisse / Summary of results

Prüfung / **Test**	**Ergebnis** / Result
Globalmigration / overall migration	bestanden / pass
Spezifische Migration von Formaldehyd (Ref.-Nr.: 17260/54880, CAS-Nr.: 50-00-0) / specific migration of formaldehyde (Ref. No: 17260/54880, CAS No: 50-00-0)	bestanden / pass
Tetrafluorethylen (Ref.-Nr.: 25120; CAS-Nr.: 116-14-3) / tetrafluoroethylene (Ref. No: 25120, CAS No: 116-14-3)	bestanden / pass
Spezifische Migration primärer aromatischer Amine / Specific migration of primary aromatic amines	bestanden / pass
Blei / Lead	bestanden / pass
Cadmium / Cadmium	bestanden / pass
PAK / PAH	bestanden / pass

Bemerkung:

Die Beurteilung erfolgt auf Basis der Prüfergebnisse der entnommenen Teilproben des vorliegenden Prüfmusters.

Die Beurteilung der Ergebnisse erfolgt anhand der genannten Anforderungen, ohne Berücksichtigung etwaiger Messunsicherheiten. Für die Bildung von Summen werden nur Messwerte oberhalb der jeweiligen Bestimmungsgrenze berücksichtigt.

Prüfungen von Mischproben von repräsentativen Teilproben wurden auf Kundenwunsch durchgeführt. Das Ergebnis bezieht sich auf die Mischprobe und nicht auf die Teilprobe.

Die Prüfung von Mischproben erfolgt auf Kundenwunsch und kann eine Abweichung von der genannten Prüfnorm darstellen.

Für Mischproben mit zwei Bestandteilen, die die Hälfte der genannten Anforderungen überschreiten, oder Mischproben mit drei Bestandteilen, die ein Drittel der genannten Anforderung überschreiten, besteht die Möglichkeit, dass ein oder mehrere Bestandteile die Anforderungen nicht bestehen. In diesen Fällen empfehlen wir eine separate Prüfung der Bestandteile.

Note:

Conclusions on pass/fail are based on the test result from the actual sampling of the received sample(s).

Conclusions are based on the relevant requirements; measurement uncertainties are not taken into account. Only results above the relevant detection limit are taken into account for the calculation of sums.

Test was conducted on composite of random parts of the item as per client's request and the test result is the overall result.

The composite sampling method is based on the client's special request and could be a modification from the testing standard.

For 2-composite mix with results exceeding one half of the relevant requirements or 3-composite mix with results exceeding one third of the relevant requirements, the composite sample may have the possibility of one or more components that can lead to a failure result, it is recommended to test on individual basis.

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Photodokumentation / Photo documentation

Teilproben-Liste / List of sample parts

Teilpr. Nr / Comp. no	**Teilproben ID** / Component-ID	**Proben-Beschreibung** / Sample-Description			**Originalproben-ID** / Original Sample ID
1	-	PTFE	Dichtungsplatte / gasket sheet		170239984

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Untersuchungsergebnisse / Analytical results

Globalmigration / overall migration

Prüfmethode / Test Method
DIN EN 1186:2002

Simulanz / simulant	3% Essigsäure / 3% acetic acid
Dauer / duration	4 Stunden / 4 hours
Temperatur / temperature	100 +/- 2°C
Ansatz / approach	6 dm²/L

Teilprobe(n) / Subsample(s)	Einheit / Unit	**Ergebnis / Result 1**
Globalmigration / overall migration	mg/dm²	1. Kontakt / 1st contact < 1
Beurteilung / Conclusion		Bestanden / Pass

Prüfmethode / Test Method
DIN EN 1186:2002

Simulanz / simulant	Olivenöl / olive oil
Dauer / duration	2 Stunden / 2 hours
Temperatur / temperature	175 +/- 2°C
Ansatz / approach	6 dm²/L

Teilprobe(n) / Subsample(s)	Einheit / Unit	**Ergebnis / Result 1**
Globalmigration / overall migration	mg/dm²	1. Kontakt / 1st contact < 1
Beurteilung / Conclusion		Bestanden / Pass

Bemerkung / Note:

Anforderung: max. 10 mg/dm² (Verordnung (EU) Nr. 10/2011)

Analysentoleranz der Methode (§ 64 LFGB B 80.30-3 (EG)):
2 mg/dm² für wässrige Prüflebensmittel
3 mg/dm² für Olivenöl und Fettersatz

Requirement: max. 10 mg/dm² (Regulation (EU) No 10/2011)

analytical tolerance of the method (§ 64 LFGB B 80.30-3 (EG)):
2 mg/dm² for aqueous simulants
3 mg/dm² for olive oil and fat substitutes

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Spezifische Migration von Formaldehyd (Ref.-Nr.: 17260/54880, CAS-Nr.: 50-00-0) / specific migration of formaldehyde (Ref. No: 17260/54880, CAS No: 50-00-0)

Prüfmethode / Test Method
DIN CEN/TS 13130-23:2005-05

Simulanz / simulant	10% Ethanol / 10% ethanol
Dauer / duration	4 Stunden / 4 hours
Temperatur / temperature	100 +/- 2°C
Ansatz / approach	6 dm²/L

Teilprobe(n) / Subsample(s)	Einheit / Unit	**Ergebnis / Result 2**
		1. Kontakt / 1st contact
Formaldehyd / formaldehyde (50-00-0)	mg/kg	< 1.0
Beurteilung / Conclusion		Bestanden / Pass

Bemerkung / Note:

Anforderung: max. 15 mg/kg Prüfsimulanz (Verordnung (EU) Nr. 10/2011)

Requirement: max. 15 mg/kg food simulant (Regulation (EU) No 10/2011)

Tetrafluorethylen (Ref.-Nr.: 25120; CAS-Nr.: 116-14-3) / Tetrafluoroethylene (Ref. No: 25120, CAS No: 116-14-3)

Prüfmethode / Test Method
Messung: Headspace-GC/MS / measurement: Headspace-GC/MS
Die Ermittlung der spezifischen Migration von Tetrafluorethylen erfolgte rechnerisch nach dem worst case Prinzip. / The determination of specific migration of tetrafluoroethylene was calculated according to the worst case principle.

Teilprobe(n) / Subsample(s)	Einheit / Unit	**Ergebnis / Result 1**
		1. Kontakt / 1st contact
Tetrafluorethylen / tetrafluoroethylene (116-14-3)	mg/dm²	< 0.01
Tetrafluorethylen / tetrafluoroethylene (116-14-3)	mg/kg Prüfsimulanz[1] / mg/kg food simulant[1]	< 0.05
Beurteilung / Conclusion		bestanden / pass

Bemerkung / Note:

[1]unter der Annahme, dass 6 dm² mit 1 kg Lebensmittel in Berührung kommen
[1]assuming that 6 dm² come into contact with 1 kg of food.

Anforderung: max. 0,05 mg/kg Prüfsimulanz (Verordnung (EU) Nr. 10/2011)

Requirement: max. 0.05 mg/kg food simulant (Regulation (EU) No 10/2011)

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Spezifische Migration primärer aromatischer Amine / Specific migration of primary aromatic amines

Prüfmethode / Test method
Extraktion: EN 645, Messung: LC-MS/MS /
extraction: EN 645, measurement: LC-MS/MS

Simulanz / simulant	3% Essigsäure / 3% acetic acid
Dauer / duration	4 Stunden / hours
Temperatur / temperature	100 +/- 2° C
Ansatz / approach	6 dm²/L

Teilprobe(n) / Subsample(s)	Einheit / Unit	**Ergebnis / Result 1**
		1. Kontakt / 1st contact
Anilin (62-53-3) / Aniline (62-53-3)	µg/l	< 2
o-Toludin (95-53-4)[a] / o-toluidine (95-53-4)[a]	µg/l	< 2
m-Toluidin (108-44-1) / m-toluidine (108-44-1)	µg/l	< 2
p-Toluidin (106-49-0) / p-toluidine (106-49-0)	µg/l	< 2
2,4-Toluylendiamin (95-80-7)[a] / 2,4-toluylendiamine (95-80-7)[a]	µg/l	< 2
2,6-Toluylendiamin (823-40-5)/ 2,6-toluylendiamine (823-40-5)	µg/l	< 2
o-Anisidin (90-04-0)[a] / o-anisidine (90-04-0)[a]	µg/l	< 2
m-Anisidin (536-90-3)/ m-anisidine (536-90-3)	µg/l	< 2
Benzidin (92-87-5)[a]/ Benzidine (92-87-5)[a]	µg/l	< 2
4,4´-Diaminodiphenylmethan (101-77-9)[a] / 4,4'-diaminodiphenylmethane (101-77-9)[a]	µg/l	< 2
4,4´Oxydianilin (101-80-4)[a] / 4,4'-oxydianiline (101-80-4)[a]	µg/l	< 2
4-Chloranilin (106-47-8)[a] / 4-chloraniline (106-47-8)[a]	µg/l	< 2
3-Chloranilin (108-42-9) / 3-chloroaniline (108-42-9)	µg/l	< 2
p-Kresidin (120-71-8)[a] / p-kresidine (120-71-8)[a]	µg/l	< 2
4-Chlor-o-toluidin (95-69-2)[a] / 4-chloro-o-toluidine (95-69-2)[a]	µg/l	< 2
2-Naphtylamin (91-59-8)[a] / 2-naphtylamine (91-59-8)[a]	µg/l	< 2
4-Aminodiphenyl (92-67-1)[a] / 4-aminodiphenyle (92-67-1)[a]	µg/l	< 2
4-Aminoazobenzol (60-09-3)[a] / 4-aminoazobenzene (60-09-3)[a]	µg/l	< 2
3,3-Dimethylbenzidin (119-93-7)[a]/ 3,3-dimethylbenzidine (119-93-7)[a]	µg/l	< 2
4,4´-Thiodianilin (139-65-1)[a] / 4,4' – thiodianiline (139-65-1)[a]	µg/l	< 5

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3,3´-Dimethyl-4,4´-diaminodiphenylmethan (838-88-0)[a] / 3,3'-dimethyl-4,4'-diaminodiphenylmethane (838-88-0)[a]	µg/l	< 2
3,3´-Dimethoxybenzidin (119-90-4)[s] / 3,3-dimethoxybenzidine (119-90-4)[a]	µg/l	< 2
3,3´-Dichlorbenzidin (91-94-1)[a] / 3,3-dichlorobenzidine (91-94-1)[a]	µg/l	< 2
4,4´-Methyl-bis(2-chloranilin) (101-14-4)[a] / 4,4'-methyl-bis(2-chloroaniline) (101-14-4)[a]	µg/l	< 2
(1,3)- / 1,4-Phenylendiamin (108-45-2 / 106-50-3) / (1,3)- / 1,4-phenylenediamine (108-45-2 / 106-50-3)	µg/l	< 2
1,2-Phenylendiamin (95-54-5) / 1,2-phenylenediamine (95-54-5)	µg/l	< 2
2,4,5-Trimethylanilin (137-17-7)[a] / 2,4,5-trimethylaniline (137-17-7)[a]	µg/l	< 2
o-Aminoazotoluol (97-56-3)[a] / o-aminoazotoluene (97-56-3)[a]	µg/l	< 2
2,4-Diaminoanisol (615-05-4)[a] / 2,4-diaminoanisol (615-05-4)[a]	µg/l	< 2
2-Amino-4-nitrotoluol (99-55-8) / 2-amino-4-nitrotoluene (99-55-8)	µg/l	< 2
2,6-Dimethylanilin (87-62-7) / 2,6-dimethylaniline (87-62-7)	µg/l	< 2
2,4-Dimethylanilin (95-68-1) / 2,4-dimethylaniline (95-68-1)	µg/l	< 2
1,5-Diaminonaphthalin (2243-62-1) / 1,5-diaminonapthalene (2243-62-1)	µg/l	< 2
4,4'-Methylen-bis(3-chlor-2,6-diethylanilin) (106246-33-7) / 4,4'-methylen-bis(3-chloro-2,6-diethylanilne (106246-33-7)	µg/l	< 2
2,4-Diamino-6-phenyl-1,3,5-triazin (91-76-9) / 2,4-diamino-6-phenyl-1,3,5-triazine (91-76-9)	µg/l	< 2
4-Ethoxyanilin (156-43-4) / 4-ethoxyaniline (156-43-4)	µg/l	< 2
3-Amino-4-methoxybenzanilid (120-35-4) / 3-amino-4-methoxybenzanilide (120-35-4)	µg/l	< 2
2-Methoxy-4-nitroanilin (97-52-9) / 2-methoxy-4-nitroaniline (97-52-9)	µg/l	< 5
5-Amino-6-methylbenzimidazolon (67014-36-2) / 5-amino-6-methylbenzimidazolone (67014-36-2)	µg/l	< 5
4-Aminobenzamid (2835-68-9) / 4-aminobenzamide (2835-68-9)	µg/l	< 5
3-Amino-4-methylbenzamid (19406-86-1) / 3-amino-4-methylbenzamid (19406-86-1)	µg/l	< 5
2-Chloranilin (95-51-2) / 2-chloroaniline (95-51-2)	µg/l	< 10
2-Ethoxyanilin (94-70-2) / 2-ethoxyaniline (94-70-2)	µg/l	< 5

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5-Chlor-2-methylanilin (95-79-4) / 5-chloro-2-methylaniline (95-79-4)	µg/l	< 5
1,3-Diiminoisoindolen (3468-11-9) / 1,3-diiminoisoindolene (3468-11-9)	µg/l	< 10
5-Chlor-2-methoxyanilin (95-03-4) / 5-chloro-2-methoxyanilin (95-03-4)	µg/l	< 5
2,5-Dichloranilin (95-82-9) / 2,5-dichloroaniline (95-82-9)	µg/l	< 10
2-Chlor-4-nitroanilin (121-87-9) / 2-chloro-4-nitroaniline (121-87-9)	µg/l	< 5
4-Chlor-2,5-dimethoxyanilin (6358-64-1) / 4-chloro-2,5-dimethoxyaniline (6358-64-1)	µg/l	< 5
2,4,5-Trichloranilin (636-30-6) / 2,4,5-trichloroaniline (636-30-6)	µg/l	< 10
4-Chlor-3-methoxyanilin (13726-14-2) / 4-chloro-3-methoxyaniline (13726-14-2)	µg/l	< 10
2,4-Dinitroanilin (97-02-9) / 2,4-dinitroaniline (97-02-9)	µg/l	< 5
4-aminotoluol-3-sulfonsäure (88-44-8) / 4-aminotoluene-3-sulfonic acid (88-44-8)	µg/l	< 5
2-Amino-1-naphthalinsulfonsäure (81-16-3) / 2-amino-1-naphthalinesulfonic acid (81-16-3)	µg/l	< 5
Dimethylaminoterephthalat (5372-81-6) / Dimethyl aminoterephthalate (5372-81-6)	µg/l	< 2
p-Anisidin (104-94-9) / p-Anisidine (104-94-9)	µg/l	< 2
3,4-Dichloranilin (95-76-1) / 3,4-Dichloraniline (95-76-1)	µg/l	< 2
1-Naphthylamin (134-32-7) / 1-Naphthylamine (134-32-7)	µg/l	< 2
2-Aminobiphenyl (90-41-5) / 2-Biphenylylamine (90-41-5)	µg/l	< 2
Butyl-Anthranilat (7756-96-9) / Butyl anthranilate (7756-96-9)	µg/l	< 2
2,4-Diaminodiphenylmethan (1208-52-2) / 2,4-Diaminodiphenylmethane (1208-52-2)	µg/l	< 2
2,2-Diaminodiphenylmethan (6582-52-1) / 2,2'-Diaminodiphenylmethane (6582-52-1)	µg/l	< 2
2-Amino-5-methylbenzoesäure (2941-78-8) / 2-Amino-5-methylbenzoic acid (2941-78-8)	µg/l	< 2
Summe / Sum	µg/l	-
Beurteilung / conclusion		bestanden / pass

Bei der Summation werden nur Ergebnisse oberhalb der Berichtsgrenze eingerechnet. /
For the summation only results above the reporting limit are taken into account.

Anforderung: nicht nachweisbar (Summe: < 10 µg/l (in Anlehnung an Verordnung (EU) Nr. 10/2011) (in Anlehnung an BfR Empfehlung XXXVI)
< 2 µg/l für die mit [a] markierten Substanzen (in Anlehnung an BfR Empfehlung XXXVI)

Requirement: not detectable (Sum <10 µg/l based on Regulation (EU) No. 10/2011) (based on BfR Recommendation XXXVI)
< 2 µg/l for the marked substances ([a]) (based on BfR Recommendation XXXVI)

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Blei / Lead

Prüfmethode / Test Method
Hausmethode , Analyse mit ICP-OES nach Aufschluss / Inhouse-method , analysis was conducted with ICP-OES after digestion

Teilprobe(n) / Subsample(s)	Einheit / Unit	**Ergebnis / Result** **1**
Blei (Pb) / Lead (Pb)	mg/kg	< 2.0
Beurteilung / Conclusion		Bestanden / Pass

Bemerkung / Note:

Anforderung: nicht gelistet in Verordnung (EU) Nr. 10/2011 (<2 mg/kg)

Requirement: not listed in Regulation (EU) No 10/2011 (<2 mg/kg)

Cadmium / Cadmium

Prüfmethode / Test Method
In Anlehnung an EN 1122:2002 , Analyse mit ICP-OES nach Aufschluss / Based on EN 1122:2002 , analysis was conducted with ICP-OES after digestion

Teilprobe(n) / Subsample(s)	Einheit / Unit	**Ergebnis / Result** **1**
Cadmium (Cd) / Cadmium (Cd)	mg/kg	< 0.5
Beurteilung / Conclusion		Bestanden / Pass

Bemerkung / Note:

Anforderung: nicht gelistet in Verordnung (EU) Nr. 10/2011 (<0,5 mg/kg)

Requirement: not listed in Regulation (EU) No 10/2011 (<0.5 mg/kg)

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PAK / PAH

Prüfmethode / Test Method
AfPS GS 2014:01 PAK , Bestimmung mittels GC-MSD / AfPS GS 2014:01 PAK , with use of GC-MSD

Teilprobe(n) / Subsample(s)	Einheit / Unit	**Ergebnis / Result** **1**
Benzo[a]anthracen / Benzo[a]anthracene (56-55-3) [1]	mg/kg	< 0.2
Chrysen / Chrysene (218-01-9) [1]	mg/kg	< 0.2
Benzo[e]pyren / Benzo[e]pyrene (192-97-2) [1]	mg/kg	< 0.2
Benzo[b]fluoranthen / Benzo[b]fluoranthene (205-99-2) [1]	mg/kg	< 0.2
Benzo[k]fluoranthen / Benzo[k]fluoranthene (207-08-9) [1]	mg/kg	< 0.2
Benzo[j]fluoranthen / Benzo[j]fluoranthene (205-82-3) [1]	mg/kg	< 0.2
Benzo[a]pyren / Benzo[a]pyrene (50-32-8) [1]	mg/kg	< 0.2
Dibenzo[ah]anthracen / Dibenzo[ah]anthracene (53-70-3) [1]	mg/kg	< 0.2
Beurteilung EU-PAK / Conclusion EU-PAHs		Bestanden / Pass
Acenaphthylen / Acenaphthylene (208-96-8)	mg/kg	< 0.2
Acenaphthen / Acenaphthene (83-32-9)	mg/kg	< 0.2
Fluoren / Fluorene (86-73-7)	mg/kg	< 0.2
Phenanthren / Phenanthrene (85-01-8)	mg/kg	< 0.2
Anthracen / Anthracene (120-12-7)	mg/kg	< 0.2
Fluoranthen / Fluoranthene (206-44-0)	mg/kg	< 0.2
Pyren / Pyrene (129-00-0)	mg/kg	< 0.2
Naphthalin / Naphthalene (91-20-3)	mg/kg	< 0.2
Benzo[ghi]perylen / Benzo[ghi]perylene (191-24-2)	mg/kg	< 0.2
Indeno[1,2,3-cd]pyren / Indeno[1,2,3-cd]pyrene (193-39-5)	mg/kg	< 0.2
Summe 18 PAK / Total 18 PAH [2]	mg/kg	-
Beurteilung (pro Einzelverbindung) / Conclusion (per single substance)		Bestanden / Pass

Bemerkung / Note:

Anforderung: nicht gelistet in Verordnung (EU) Nr. 10/2011 (<0,2 mg/kg)
Requirement: not listed in Regulation (EU) No 10/2011 (<0.2 mg/kg)

[1]PAK gemäß der EU VO Nr. 1272/2013 zur Erweiterung des Anhang XVII EU VO Nr. 1907/2006 gültig ab 27. Dezember 2015
[1]PAH according to the Commission Regulation (EU) No 1272/2013 amending Annex XVII to Regulation (EC) No 1907/2006 effective from December 27, 2015

[2]Bei der Summation werden nur Ergebnisse oberhalb der Berichtsgrenze eingerechnet
[2]For the summation only results above the reporting limit are taken into account.

*** Ende des Berichts *** / *** End of test report ***

The analytical findings are only valid for the sample as analyzed. Written acknowledgement for publication and duplication of our analytical reports for promotional purpose, as well as fractional use for other purposes mandatory. Electronically submitted results are for your information only. For legally binding results refer to the originally signed analytical report. Numbers following „<“ represent limits of quantification. Determination of parameters marked with * was performed with a cooperation partner. Please note that the analysis was fully or partially conducted at the laboratory facilities of Institut Fresenius which are accredited according to DIN EN ISO/IEC 17025. These laboratory facilities are not explicitly accounted as GMP-areas.