Rotselaar, 16-dec-2019

DECLARATION OF CONFORMITY CROWN CORKS

Products to which this document applies:

2126011ALI CC 26 mm TP PVC Free Aliénor Gold/Black, 212601B CC 26 mm TP PVC Free Gold Shiny, 212601CS CC 26 mm TFS PVC Free Gold, 212602 CC 26 mm TFS PVC Free Silver, 212602TP CC 26 mm TP PVC Free Silver Shiny, 212603 CC 26 mm TP PVC Free Copper, 212604 CC 26 mm TFS PVC Free White, 212605 CC 26 mm TFS PVC Free Yellow, 2126051006 CC 26 mm TFS PVC Free Abers, 212606 CC 26 mm TFS PVC Free Red, 212606BREST CC 26 mm TFS PVC Free Brestoizh Full Colour, 212606P202C CC 26 mm TFS PVC Free Burgundy P202C/Silver, 212607 CC 26 mm TFS PVC Free Blue, 212607P279C CC 26 mm TFS PVC Free Blue P279C, 212608 CC 26 mm TFS PVC Free Green, 212608P7481C CC 26 mm TFS PVC Free Green P7481C, 212609 CC 26 mm Burgundy, 212609P215C02 CC 26 mm TFS PVC Free Pink/Silver, 212610 CC 26 mm TFS PVC Free Black, 21261004TOUSSAINT CC 26 mm TFS PVC Free Tous Saint Black/White, 212611 CC 26 mm TFS PVC Free Brown, 21261210KANA CC 26 mm TFS PVC Free Kanarfoll Cream/Black, 212616P205C CC 26 mm TFS PVC Free Pink P205C, 212618 CC 26 mm TFS PVC Free Orange, 2129016BOLSKOV CC 29 mm Bolskov Gold/Red, 212901OSLINER CC 29 mm TFS PVC Free Oxygen Scavenger Gold, 212901PF CC 29 mm TFS PVC Free Gold, 212902OSLINER CC 29 mm TFS Oxygen Scavenger Silver, 212902PF CC 29 mm TFS PVC Free Silver, 212904OSLINER CC 29 mm TFS Oxygen Scavenger White, 212904PF CC 29 mm TFS PVC Free White, 212906OSLINER CC 29 mm TFS Oxygen Scavenger Red, 212906PF CC 29 mm TFS PVC Free Red, 212907OSLINER CC 29 mm TFS Oxygen Scavenger Blue, 212907PF CC 29 mm TFS PVC Free Blue, 212908OSLINER CC 29 mm TFS Oxygen Scavenger Green, 212908PF CC 29 mm TFS PVC Free Green, 212910OSLINER CC 29 mm TFS Oxygen Scavenger Black, 212910PF CC 29 mm TFS PVC Free Black, 212911OSLINER CC 29 mm TFS Oxygen Scavenger Brown, 212911PF CC 29 mm TFS PVC Free Brown

Eurocap N.V. confirms that our crowns as delivered to ***Malterie du Chateau,***
are produced per HACCP methodology and corresponding to the international standards for quality management and quality security. We guarantee that the Quality System followed to produce our products is subject to the requirements of these standards. Our crowns are suitable for water, beer, soft and energy drinks and we declare that they are in line with all relevant European legislation:

- EC 1935/2004
- EC 2023/2006
- EU 10/2011 and subsequent amendments
- EC 450/2009
- EC 1895/2005
- EU 2015/174

QC Manager,

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Eurocap N.V. is not responsible for inexpert use or storage.

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February 19, 2015

Product Safety and Regulatory Compliance

Commission Regulation (EU) No 10/2011: Statement for DARAFORM® 6411MF

(F860-1)

When properly applied and if necessary dried or cured in accordance with our application recommendations, we confirm that this product, as supplied by Grace Materials Technologies is compliant with Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food [and amendments].

EU Food Law - Non-Confidential Disclosure: Statement for DARAFORM® 6411MF

(F800-19)

General Condition Section

This product is manufactured under good manufacturing practices so that the finished products containing it can comply with the provisions of the EU Framework Regulation (EC) No.1935/2004 on food-contact materials. However, it is the responsibility of manufacturer of the finished food-contact article to ensure that all relevant regulatory or legislative limitations and specifications are met, including compliance with Article 3 of the Framework Regulation.

Specific statement

To assist customers in the assessment of their packaging against the requirements of EU Regulation (EC) No.1935/2004 of the European Parliament and of the Council of 27 October, 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, the following information is given for this product, as supplied by Grace Materials Technologies :

It is manufactured only from materials in compliance with either (i) Commission Regulation (EU) No 10/2011 [and amendments] or (ii) a valid member state regulation such as the Netherlands VGB or BfR Recommendations in Germany.

As a consequence, in addition to the overall migration limit of 10 mg/dm2 of food contact surface, specific restrictions which apply are complied with.

With reference to the EU status, when properly applied and if necessary dried or cured in accordance with our application recommendations, we confirm this product is compliant with EU Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

This is confirmed by tests carried out at an independent testing laboratory (See enclosed) which confirm satisfactory migration and organoleptic performance of this product.

Enclosure: SQTS general statement dated 3 October 2014

This product is suitable for use with aqueous and alcoholic beverages undergoing pasteurization or hot fill processes. It must not be used for fatty or oily foodstuffs.

EU Food Law: Dual Use Additives: Statement for DARAFORM® 6411MF

(F820)

We confirm that additives where they have a dual use as a direct food additive or are authorised as a food additive or flavouring (Article 5a and Council Directives 89/107/EEC and 88/388/EEC respectively refer) are known to be present in this product as supplied by Grace Materials Technologies.

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EU REGULATION 2023/2006: Statement for DARAFORM® 6411MF

(F744)

EU REGULATION 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food

EU Regulation 2023/2006 concerns good manufacturing practice of materials and articles intended to come into contact with food throughout the supply chain. This came into force in January 2007 and has been applied since 1st August 2008.

Grace Materials Technologies manufactures can sealants and seaming compounds, closures and can coating products at locations in EU.

These locations employ management systems that control:

a) Raw material specification and approval
b) Procedures for the standardization of manufacturing processes
c) Personnel with clearly identified responsibilities for quality assurance
d) Quality control to ensure any deviations are captured and corrective actions are instigated
e) Control procedures for documents that affect on product safety, compliance and quality

With specific reference to the Annex, Section 1, external coatings products are formulated so that when applied in accordance with our recommendations, none of the starting substances are expected to be transferred to the food contact surface during application.

It is the opinion of Grace Materials Technologies that we meet the requirements of good manufacturing practice as laid out in EU Regulation 2023/2006.

Supporting data: Statement for DARAFORM® 6411MF

(F802-3)

The attached extract from the third party laboratory certificate for this product shows the details of the overall migration into different food simulants as well as the details of the specific migration and the identity of dual use additives.

Enclosure: Supporting data taken from SQTS Examination Report dated 3 October 2014

US FDA: Statement for DARAFORM® 6411MF

(F841)

When properly applied and if necessary dried or cured in accordance with our application recommendations, we confirm that this product, as supplied by Grace Materials Technologies is compliant with US FDA 21 CFR 177.1210 - Closures with sealing gaskets for food containers.

US FDA & EU Food Law: Statement for DARAFORM® 6411MF

(F661-1)

Please see the enclosed supporting third party laboratory certificate for this product as supplied by Grace Materials Technologies.

Enclosure: SQTS Examination Report dated 3 October 2014

Disclaimer:
The above statement(s) are based on our current knowledge and experience and on legislation in effect on the date above. This compliance statement does not warrant against modifications of this product resulting from its processing or from the addition of other products, nor against any inadequate use and/or storage of this product or the materials and articles containing it. The present statement also does not warrant compliance with legislation changed after the date above.

This document has been created electronically and is valid without signature.

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03. October 2014

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Your Reference:	Our Reference:
07.05.2014 / MPC	2014L18886/1

Examination of Closure DARAFORM®6411MF

General Statement

We have been appointed by your letter dated 07 May 2014 to analyse and to assess the closure compound DARAFORM 6411MF with respect to current EU and FDA food legislation.

Product data:

Sample: Caps, sealed with DARAFORM 6411MF,

Intended use: According to your information the product is used as sealant in closures for beverages which will be hot filled and pasteurized

Documents: Composition (formulation)

Analytic

The overall migration was determined by our chemical analysis. For this the samples were exposed to aqueous, acidic and alcoholic simulants under test conditions which are suitable to simulate the influence of foodstuff. The testing conditions (1h 100° C + 10d 40° C) were selected according to Commission Regulation (EU) No. 10/2011 resp. to FDA 21 CFR § 177.1210 with 2h 250° F and 2h 150°F. For Specific migration all substances were analysed, which are subject to a restriction of use. For sensorial analysis tap water was used.

Assessment

Under the test conditions selected, with the used aqueous and non-aqueous simulants there was no overall migration which would give reason for concern. When used as intended, the determined values fulfil the requirements of the Regulation (EU) No 10/2011 and FDA 21 CFR § 177.1210.

The examination of the migrates showed no specific migration of the analysed substances. Therefore, the requirements of the Regulation (EU) No. 10/2011 are fulfilled.

Dual use additives do not migrate, or because of their low concentration in the material and taking into account the applied surface volume ratio they do not migrate according to our opinion in amounts which could have technological effects in the food.

The sensory evaluation showed that the product does not influence the appearance and the odour. For flavour there was only a slightly observable deviation within the typical tolerance. A subsequent derogation in contact with food can be excluded. The assessment was done according to DIN 10955.

General Assessment

Due to the evaluation based on the submitted documents (formulation), the composition derived from it and the previously mentioned analysis results, the present product fulfils the requirements of the Regulation (EC) No. 1935/2004 article 3 provided it is used as intended. Under the normal and foreseeable conditions of use, the product DARAFORM 6411MF does thereafter not add components to food in quantities that endanger the human health, cause an untenable change of the composition or an impairment of the organoleptic characteristics of the food.
The closure compound DARAFORM 6411MF complies also with the requirements of Regulation (EU) No 10/2011 and with the US FDA 21 CFR § 177.1210.

This assessment does generally not relieve the user of the product DARAFORM 6411MF to accomplish own migration testing. This report exclusively refers to the analysed samples. In the case of a change of the raw materials, the raw material composition of the product, the legal regulations or new toxicological findings, this evaluation loses its validity.

References

- Commission Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004
- Commission Regulation (EU) No. 10/2011 of 14 January 2011
- US FDA CFR 21 § 177.1210
- DIN 10955, edition June 2004

Dietikon, 03 October 2014

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03. October 2014

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France

Your Reference:	Our Reference:
07.05.2014 / MPC	2014L18886/1

Examination Report of Closure DARAFORM® 6411MF

We have been appointed by your letter dated 07 May 2014 to analyse and to assess the closure compound DARAFORM® 6411MF with respect to current EU and FDA food legislation.

Product data:

Sample: Caps, sealed with DARAFORM® 6411MF,
Intended use: According to your information the product is used as sealant in closures for beverages which will be hot filled and pasteurized
Documents: Composition (formulation)

Analytic

Overall migration

The overall migration was determined by our chemical analysis. For this the samples were exposed to aqueous, acidic and alcoholic simulants under test conditions which are suitable to simulate the influence of foodstuff. The testing conditions (1h 100° C + 10d 40° C) were selected according to Commission Regulation (EU) No. 10/2011 resp. to FDA 21 CFR § 177.1210 with 2h 250° F and 2h 150°F.

Specific migration

For Specific migration all substances were analysed, which are subject to a restriction of use according to EN 13130 or in-house methods.
The testing conditions (1h 100° C + 10d 60° C) were selected according to Commission Regulation (EU) No. 10/2011
Additionally, a 10 µg/kg screening by GC/MS was performed out of 50% Ethanol.

Sensory evaluation

For the sensory evaluation, tap water was exposed to the sample for 1 h 100 °C + 10 d 40 °C. As a blank, tap water that had never been in contact with the product was used. The assessment is done according to DIN 10955.

Results of the examinations

Examination of the formulation

For the following starting substances restrictions have to be considered:

Starting substance	CAS/ PM-Ref No	Restriction	Reference / Comment
Butadiene	13630	SML = 0.01 mg/kg	Reg. 10/2011
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	68320	SML = 6 mg/kg	Reg. 10/2011
2-ethyl-1-hexanol	17050	SML = 30 mg/kg	Reg. 10/2011
Lithium	n.a.	SML = 0.6 mg/kg	Reg. 10/2011
Zinc oxide	96240	SML = 25 mg/kg	Reg. 10/2011
2,4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tertbutylanilino)-1,3,5-triazine	40000	SML = 30 mg/kg	Reg. 10/2011
1,1,1-trimethylolpropane	13380	SML = 6 mg/kg	Reg. 10/2011
Zirconium oxide		SML = 0.01 mg/kg	Reg. 10/2011
2,6-Di-tert-butyl-p-cresol (BHT)	000128-37-0	SML = 3 mg/kg	Reg. 10/2011

The formulation check was done according to EU law as well as to US FDA CFR 21, Parts 175.300

Dual Use Additive:

Following Dual Use Additive are used. In case no SML is fixed, the migration value is covered via the overall migration, in any other case the substance is specifically determined.

Starting substance	CAS No PM-Ref No	Restriction	E-Number
2,6-Di-tert-butyl-p-cresol (BHT)	000128-37-0	SML = 3 mg/kg	E 321
Silicon dioxide	86240	No	E 551
(Calcium) stearate	89040	No	E 470a
Titanium dioxide	93440	No	E 171

Overall migration:

Simulant	Test conditions (Time/Temperature)	Dry Residue of Migrates in mg/lid
20 % Ethanol	1 h 100 °C + 10 d 40 °C	3
3 % Acetic acid	1 h 100 °C + 10 d 40 °C	< 1
50 % Ethanol	1 h 100 °C + 10 d 40 °C	< 1
Dist. water	2 h 250 °F	< 1
8% Ethanol	2 h 150 °F	< 1

Specific migration:
The specific migration value [mg substance / kg food] was calculated that 200 ml is in contact with a packaging area of 195 cm^2. For any other surface-area-to-volume ratio, the resulting specific migration value is different. The value for the actual packaging should be calculated by the producer.

Method overview:

Starting substance	CAS No PM-Ref No	Method	Detection
Butadiene	13630	Headspace	Headspace-GC/MS
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	68320	Migration (50% Ethanol)	GC/MS - Screening
2-ethyl-1-hexanol	17050	Headspace	Headspace-GC/MS
Lithium	n.a.	Migration (3% Acetic Acid)	ICP/MS - Screening
Zinc oxide	96240	Migration (3% Acetic Acid)	ICP/MS - Screening
2,4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tertbutylanilino)-1,3,5-triazine	40000	Migration (50% Ethanol)	LC/MS - Screening
1,1,1-trimethylolpropane	13380	Migration (50% Ethanol)	GC/MS - Screening
Zirconium oxide		Migration (3% Acetic Acid)	ICP/MS - Screening
2,6-Di-tert-butyl-p-cresol (BHT)	000128-37-0	Migration (50% Ethanol)	GC/MS - Screening
Silicon dioxide	86240	Overall migration	Gravimetric
(Calcium) stearate	89040	Overall migration	Gravimetric
Titanium dioxide	93440	Overall migration	Gravimetric

GC/MS Screening: 50 % ethanol (1 h 100 °C + 10 d 60 °C)
After concentrating the 50 % ethanol migration solution (factor 10), a mix of internal standards was added (IS 1: 10 µg/kg D4-DBP; IS 2: 100 µg/kg D4-BBP, IS 3: 10 µg/kg 2-ethylhexyl diphenyl phosphate and IS 4: 100 µg/kg D4-DnNP) and the migration solution was analysed using the GC-MS screening procedure for ingredients and contaminants. The detected migrants were compared with the MS database NIST and calculated with the 100 µg/kg internal standards.
No relevant substances above 10 µg/kg were detected. This includes also possible white mineral oil residues, which were not detectable above 10 µg/kg.

GC/MS specific testing out of 50 % ethanol (1 h 100 °C + 10 d 60 °C)

Substance	Result [mg/dm²]	LoD [mg/dm²]	Result [mg/kg]	Limit
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	n.d.	0.003	n.d.	SML = 6 mg/kg
1,1,1-trimethylolpropane	n.d.	0.1	n.d.	SML = 6 mg/kg
2,6-Di-tert-butyl-p-cresol (BHT)	n.d.	0.003	n.d.	SML = 3 mg/kg

LC/MS specific testing out of 50 % ethanol (1 h 100 °C + 10 d 60 °C)

Substance	Result [mg/dm²]	LoQ [mg/dm²]	Result [mg/kg]	Limit
2,4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tertbutylanilino)-1,3,5-triazine	n.d.	0.001	n.d.	SML = 30 mg/kg

ICP/MS: 3 % acetic acid (1 h 100 °C + 10 d 60 °C)

Substance	Result [mg/lid]	LoQ [mg/lid	Result [mg/kg]	Limit
Zinc	n.d.	1	n.d.	SML = 25 mg/kg
Zirconium	n.d.	0.01	n.d.	SML = 0.01 mg/kg
Lithium	n.d.	0.01	n.d.	SML = 0.6 mg/kg

Headspace-GC/MS*:

Substance	Result [mg/kg material]	LoD [mg/kg food]	Result [mg/kg food]	Limit
Butadiene	n.d.	0.01	n.d.	SML = 0.01 mg/kg
2-ethyl-1-hexanol	n.d.	0.001	n.d.	SML = 30 mg/kg

n.d. = not detectable, LoD = Limit of detection, LoQ = Limit of quantificaton

Sensory evaluation:

Simulant	Surface-/Volume-Ratio	Appearance	Odour	Taste
Tap water: 1 h 100 °C + 10 d 40 °C	1 cm^2 : 2 ml	0	0	1

0 = no deviation observable, 1= deviation slightly observable, 2 = slight deviation, 3 = considerable deviation, 4 = strong deviation

Assessment

Under the test conditions selected, with the used aqueous and non-aqueous simulants there was no overall migration which would give reason for concern. When used as intended, the determined values fulfil the requirements of the Regulation (EU) No 10/2011 and FDA 21 CFR § 177.1210.
The examination of the migrates showed no specific migration of the analysed substances. Therefore, the requirements of the Regulation (EU) No. 10/2011 are fulfilled.
Dual use additives do not migrate, or because of their low concentration in the material and taking into account the applied surface volume ratio they do not migrate according to our opinion in amounts which could have technological effects in the food.
The sensory evaluation showed that the product does not influence the appearance and the odour. For flavour there was only a slightly observable deviation within the typical tolerance. A subsequent derogation in contact with food can be excluded. The assessment was done according to DIN 10955.

General Assessment

Due to the evaluation based on the submitted documents (formulation), the composition derived from it and the previously mentioned analysis results, the present product fulfils the requirements of the Regulation (EC) No. 1935/2004 article 3 provided it is used as intended. Under the normal and foreseeable conditions of use, the product DARAFORM® 6411MF does thereafter not add components to food in quantities that endanger the human health, cause an untenable change of the composition or an impairment of the organoleptic characteristics of the food.
The closure compound DARAFORM® 6411MF complies also with the requirements of Regulation (EU) No 10/2011 and with the US FDA 21 CFR § 177.1210.
This assessment does generally not relieve the user of the product DARAFORM® 6411MF to accomplish own migration testing. This report exclusively refers to the evaluated product. In the case of a change of the raw materials, the raw material composition of the product, the legal regulations or new toxicological findings, this evaluation loses its validity.

References

- Commission Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004
- Commission Regulation (EU) No. 10/2011 of 14 January 2011
- US FDA 21 CFR § 177.1210
- DIN 10955, edition June 2004

Dietikon, 03 October 2014

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Dep. Head SQTS

Supporting data taken from SQTS examination report dated 3 October 2014 for DARAFORM® 6411MF

- **Overall migration:**

Simulants	t/T conditions	Dry residue of migrates mg/lid	Overall Migration Result*(mg/ dm2 of food contact surface)
3% acetic acid	1 h 100℃ + 10 d 40℃	< 1	< 0.5
20% ethanol	1 h 100℃ + 10 d 40℃	3	1.5
50% ethanol	1 h 100℃ + 10 d 40℃	< 1	< 0.5

** This value is based on measured migration per crown cork and total internal area of 1,95 dm^2.*

Simulants	t/T conditions	Dry residue of migrates mg/lid	Overall Migration Result*(mg/kg)
Dist. water	2h 121℃	< 1	< 5
8% ethanol	2h 65℃	< 1	< 5

** This value is based on measured migration per crown cork and typical parameters of a food weight of 0.2 kg.*

- **Specific migration:**

Substance	Substance Reference	Specific Migration Result*(mg/kg)	Specific Migration Limit (SML) (mg/kg)	SML Reference
Butadiene	13630	n.d. (< 0.01 in product)	0.01 ND (< 1 mg/kg in final product)	Reg. (EU) No 10/2011
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	68320	n.d. (< 0.01)	6	Reg. (EU) No 10/2011
2-ethyl-1-hexanol	17050	n.d. (< 0.0011)	30	Reg. (EU) No 10/2011
1,1,1-trimethylolpropane	13380	n.d. (< 0.1)	6	Reg. (EU) No 10/2011
2,6-Di-tert-butyl-p-cresol (BHT)	46640	n.d. (< 0.01)	3	Reg. (EU) No 10/2011
2,4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	40000	n.d. (< 2)	30	Reg. (EU) No 10/2011
Zinc oxide (as zinc)	96240	< 5	25	Reg. (EU) No 10/2011
Lithium		< 0.05	0.6	Reg. (EU) No 10/2011

** This value is based on measured migration per crown cork and typical parameters of a food weight of 0.2 kg.*

- **Specific migration – other substances:**

Substance	Substance Reference	Specific Migration Result(mg/kg)	Limit of quantification (mg/kg)
Zirconium oxide (as zirconium)		< 0.05	0.05

- **Dual use additives:**

Substance	Substance Reference	Food additive number
Titanium dioxide	93440	E171
2,6-Di-tert-butyl-p-cresol (BHT)	46640	E321
(Calcium) stearate	89040	E470a
Silicon dioxide	86240	E551