



ANCERVILLE, le 2 juillet 2020

## CERTIFICAT DE CONFORMITE DES CAPSULES COURONNE

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Appellation	Code EAN lot de 250	Code EAN lot de 1000	Code EAN lot carton
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Caps cour. Dia. 26 coul. blanc	3700800200040	3700800200262	
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- EC 1935/2004
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- EC 450/2009
- EC 1895/2005
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page 1 of 9

Your ref.

Dr. Stüber/March 12, 2019

Our ref./document

CKCK07-049 (1905-129)

telephone

0531-23899-0

*Translation of our test report CKCK06-049 of 23 April 2019***Examination of Lining Compound SVELON® 855 B**

We were appointed with the evaluation of **Lining Compound SVELON® 855 B** with regard to legal requirements for food contact materials.

According to your information the material is intended to be used as sealant in crown corks in contact with mineral water, lemonade, beer, wine, champagne as well as further alcoholic beverages with maximum content of 50 vol% ethanol which will be pasteurized at 68 °C for 20 min (in case of beer) and stored at ambient temperature for several months.

In order to carry out the examinations we received crown corks with the mentioned lining compound.

The test specimens were brought into contact with aqueous solvents under test conditions which are suitable to simulate the influence of foodstuff.

The conditions for testing were applied in accordance with Regulation (EU) No 10/2011, which is valid for plastic food contact materials and articles.

In applying 21 CFR 177.1210 of the US FDA Regulations, the extraction into dist. water and 8 % ethanol was determined.

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.



## PROCEDURE OF THE EXAMINATIONS

### 1. Evaluation of the lining compound composition

The composition of **Lining Compound SVELON® 855 B** was disclosed to the testing laboratory. The composition has been checked with regard to possible restrictions for the use of the applied starting substances for food contact applications. The evaluation of the compositional data covered all starting substances for which the chemical identity was disclosed to the testing laboratory. For each substance it was checked whether the substance is evaluated for food contact applications according to the requirements of the European Food Safety Authority (EFSA). The evaluations are mentioned for instance in the Food Contact Materials Database of the EU Commission, DG Santé, Regulation (EU) No 10/2011 and 21 CFR 177.1210 of the US FDA Regulations. Based on the results of the composition evaluation the required tests for specific migration and residual monomer contents in the lining compound have been selected. In addition the migrates were tested for amounts of metals and metalloids in accordance with Regulation (EU) No 10/2011, Annex II 1.

### 2. Overall migration

The overall migration data were determined as dry residues of the migrates of the lining compound coming into contact with simulants. The organic components of the dry residue were determined as their chloroform soluble parts according to the requirements of 21 CFR 177.1210.

### 3. Analysis of the migrates

Each substance was analysed with the simulant which is regarded as the strictest migration solution due to chemical and/or physical properties of the resp. substance.

The migrates of the lining compound were analysed for Additive A\*, Additive B\* and metals and metalloids.

Additive A\* was determined by RP-HPLC with UV-detection.

The migrates were examined for aluminium, lithium, zirconium and further metals resp. metalloids by ICP-MS.

The examination of the specific migration of Additive B\* was not carried out. Instead the overall migration under conditions of specific migration was examined and the residue was determined gravimetrically because the substance is not volatile.

\*The identity of the components is known to the testing laboratory. It is kept under confidentiality by the raw material supplier.

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.

#### 4. Extraction test of the lining compound

The compound was extracted with DMAA. The extract was examined for residual 1,3-butadiene by headspace gaschromatography and mass specific detection.

After extraction with methanol the extract was examined for residual Monomer A\* by gaschromatography and mass specific detection.

The compound was examined for residual Monomer B\* by headspace gaschromatography and mass specific detection.

After extraction and titration the sealing compound was examined for peroxides\*.

#### 5. Sensory evaluation

The lining compound was brought into contact with the flavour sensitive test solutions tap water and mineral water. The contact was carried out after storage for 10 d 40 °C. The sensory evaluation was carried out as pairwise comparative test by a taste panel with particular experience. As blanks we used tap water and mineral water which had not been in contact with the lining compound. The evaluation was carried out in accordance with DIN 10 955 (German Institute for Standardisation).

### RESULTS OF THE EXAMINATIONS

#### 1. Evaluation of the lining compound composition

According to the results of our evaluation all starting substances, with the exception of the peroxides\* and zirconium, used for manufacturing the **Lining Compound SVELON® 855 B** are evaluated according to the requirements of the EFSA and are permitted according to Regulation (EU) No 10/2011 for the use in contact with foods.

The peroxides\* are a processing aids which are not regarded as additives in the sense of Regulation (EU) No 10/2011 but are allowed according to Art 6 (4)b.

According to the results of our assessment no raw materials are used for manufacturing the compound which may release primary aromatic amines.

All of the starting substances, with the exception of one Monomer\*, are permitted according to 21 CFR 177.1210 of the US FDA Regulations.

\*The identity of the components is known to the testing laboratory. It is kept under confidentiality by the raw material supplier.

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.



According to the result of our check the following starting substances for which restrictions have been expressed are used:

Starting substance	FCM No	Restriction	Remark
Additive A*	-	SML = 6 mg/kg	-
Additive B*	-	SML(T) = 30 mg/kg	-
Aluminium	-	SML = 1 mg/kg	-
Lithium	-	SML = 0.6 mg/kg	-
Zirconium	-	< 10 ppb	CEPE CoP Art. 5
Zinc	-	SML = 5 mg/kg	-
1,3-butadiene	223	QM = 1 mg/kg FP	-
Monomer A*	-	SML = 5 mg/kg	-
Additive C*	-	SML = 0.6 mg/kg	Solvent
Monomer C*	-	SML = 6 mg/kg	-
Peroxides*	-	SML = 0.05 mg/kg (O)	Res. AP (92) 2 Polymerisation aid
Additive D*	-	SML = 3 mg/kg	-

Taking the concentration in the compound into account even under conditions of total migration Additive D\* and Monomer C\* will not exceed their specific migration limits (SML) in the simulants or food.

According to the results of our composition check titanium dioxide and four further additives\* are used as dual use additives in the composition. These additives do not migrate or because of their low concentration in the material they do not migrate in amounts which could have technological effects in the food.

## 2. Overall migration

Simulants	t/T conditions	Dry residue of migrates mg/cc	Chloroform soluble parts of dry residue mg/cc
3 % acetic acid	10 d 40 °C	< 1.0	-
50 % ethanol	10 d 40 °C	< 1.0	-

\*The identity of the components is known to the testing laboratory. It is kept under confidentiality by the raw material supplier.

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.

Simulants	t/T conditions	Dry residue of migrates	Chloroform soluble parts of dry residue
		mg/cc	mg/cc
Dist. water	24 h 49 °C	< 1.0	0.1
8 % ethanol	24 h 49 °C	< 1.0	< 0.1

cc = crown cork

### 3. Analysis of the migrates

	Simulants	t/T conditions	Results
Additive A*	95 % ethanol	10 d 60 °C	n.d. (< 0.1 mg/cc)
Additive B*	3 % acetic acid 50 % ethanol	10 d 60 °C 10 d 60 °C	n.d. (< 1.0 mg/cc) 1.5 mg/cc
Aluminium**	3 % acetic acid	10 d 60 °C	n.d. (< 0.005 mg/cc)
Lithium**	3 % acetic acid	10 d 60 °C	n.d. (< 0.001 mg/cc)
Zirconium**	3 % acetic acid	10 d 60 °C	n.d. (< 0.001 mg/cc)

cc = crown cork

n.d. = not detectable

\*\*Examination carried out by accredited subcontractor

Metal resp. metalloids**	Simulant	t/T conditions	Results
Barium (Ba)	3 % acetic acid	10 d 60 °C	n.d. (< 0.001 mg/cc)
Iron (Fe)	3 % acetic acid	10 d 60 °C	n.d. (< 0.001 mg/cc)
Copper (Cu)	3 % acetic acid	10 d 60 °C	n.d. (< 0.001 mg/cc)
Cobalt (Co)	3 % acetic acid	10 d 60 °C	n.d. (< 0.001 mg/cc)
Zinc (Zn)	3 % acetic acid	10 d 60 °C	n.d. (< 0.001 mg/cc)
Manganese (Mn)	3 % acetic acid	10 d 60 °C	n.d. (< 0.001 mg/cc)
Nickel (Ni)	3 % acetic acid	10 d 60 °C	n.d. (< 0.001 mg/cc)

cc = crown cork

n.d. = not detectable

\*\*Examination carried out by accredited subcontractor

\*The identity of the components is known to the testing laboratory. It is kept under confidentiality by the raw material supplier.

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.

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#### 4. Extraction test

##### DMAA extraction, Headspace GC-MS

	Result
1,3-butadiene	n.d. (< 0.001 mg/cc)

##### Methanol extraction, GC-MS

	Result
Monomer A*	n.d. (< 0.001 mg/cc)

##### Headspace GC-MS

	Result
Monomer B*	n.d. (< 0.001 mg/cc)

##### Extraction and titration

	Result
Peroxides*	n.d. (< 0.007 mg/cc)

cc = crown cork  
n.d. = not detectable

#### 5. Sensory evaluation

Simulant t/T conditions	Surface/volume ratio	Appearance	Odour	Flavour
Tap water 10 d 40 °C	1 cc : 100 ml	0	0	0
Mineral water 10 d 40 °C	1 cc : 100 ml	0	0	0

cc = crown cork

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

\*The identity of the components is known to the testing laboratory. It is kept under confidentiality by the raw material supplier.

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.

## EVALUATION

### 1. Evaluation of the lining gasket composition

**Lining Compound SVELON® 855 B** contains 12 starting substances for which restrictions have to be regarded when the sealant is used in contact with foodstuffs. All starting substances, with the exception of the peroxides\* and zirconium, are evaluated according to EFSA requirements for food contact applications. According to our best knowledge these substances are not categorised as CMR substances. According to current interpretation of the EU food law zirconium may be used in food contact applications if its migration into foodstuff does not exceed a concentration of 10 µg/kg (ref. CEPE Code of Practice, art 5). According to Council of Europe Resolution AP 92 (2) a limit of 0.05 mg/kg for peroxides must not be exceeded.

### 2. Overall migration

Assuming that the lining compound is used for a crown cork with a food contact surface of 5 cm<sup>2</sup> applied onto a 100 ml glass bottle with a total internal surface of approx. 150 cm<sup>2</sup> the following overall migration data in mg/dm<sup>2</sup> resp. mg/l can be calculated:

Simulants	t/T conditions	Dry residue of migrates mg/dm <sup>2</sup>	Chloroform soluble parts of dry residue mg/dm <sup>2</sup>
3 % acetic acid	10 d 40 °C	< 0.7	-
50 % ethanol	10 d 40 °C	< 0.7	-

Simulants	t/T conditions	Dry residue of migrates mg/l	Chloroform soluble parts of dry residue mg/l
Dist. water	24 h 49 °C	< 10	2.0
8 % ethanol	24 h 49 °C	< 10	< 1.0

Taking the small amount of lining compound of approx. 5 cm<sup>2</sup> applied to one crown cork for a 100 ml bottle into account the overall migration data are below the limit of 10 mg/dm<sup>2</sup> according to Regulation (EU) No 10/2011.

They are also lower than the limits mentioned in 21 CFR 177.1210 of the US FDA Regulations concerning lining compound.

\*The identity of the components is known to the testing laboratory. It is kept under confidentiality by the raw material supplier.

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.



### 3. Analysis of the migrates

The analysis of the migrates showed no relevant specific migration of Additive A\*, aluminium, lithium and zirconium.

Metals and metalloids were not detectable. The requirements according to Regulation (EU) No 10/2011, Annex II 1. are met.

Based on the application of one crown cork on a 100 ml bottle the test result of the gravimetric determination is far below the specific migration limit for Additive B\* of 30 mg/kg.

### 4. Extraction test

The examination of the lining compound did not show detectable residues of 1,3-butadiene, Monomer A\*, Monomer B\* and peroxides\*.

### 5. Sensory evaluation

Under test conditions the lining compound does not deliver any opacifying or colouring agents to the test solution applied. There is no influence of off-odour and off-flavours in the test solutions. Consequently, on account of the sensory evaluation no off-odour and off-flavour changes have to be expected which would adversely affect aqueous, acidic or low alcoholic food.

With respect to the examinations carried out, the **Lining Compound SVELON® 855 B** as compound material for crown corks in contact with mineral water, lemonade, beer, wine, champagne as well as further alcoholic beverages with maximum content of 50 vol% ethanol which will be pasteurized at 68 °C for 20 min and stored at ambient temperature for several months, was evaluated as follows:

Under the applied test conditions with different simulants there was no overall migration detectable which would give reasons for concern. Taking the small compound surface into account which will come into direct food contact the values being obtained are below the limit of 10 mg/dm<sup>2</sup> according to Regulation (EU) No 10/2011.

The examination of the lining compound showed that there are no reasons to assume migration of health-hazardous parts from the sealant into food.

Under the conditions of intentional or foreseeable use no adverse effect from the lining gasket on odour and/or flavour is to be expected.

\*The identity of the components is known to the testing laboratory. It is kept under confidentiality by the raw material supplier.

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.

Assuming the application as a constituent of a food contact material according to § 2 (6) of the Lebensmittel- und Futtermittelgesetzbuch (LFGB) (German Law Book on Foodstuff and Feeds) taking into account the above mentioned surface/volume ratio the **Lining Compound SVELON® 855 B** is in compliance with the requirement according to Art 3 Regulation (EC) No 1935/2004 in connection with Regulation (EU) No 10/2011 as well as § 30 and § 31 (1) LFGB.

The lining compound complies with requirements according to 21 CFR 177.1210 of the US FDA Regulations.

EUROFINS INSTITUT NEHRING GmbH



Dr. Britta Steinhaus  
Analytical Service Manager

\*The identity of the components is known to the testing laboratory. It is kept under confidentiality by the raw material supplier.

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.

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Your ref.

Dr. Stüber; March 12, 2019

Our ref./document

STST20-049 (1912-011)

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**Examination of Lining Compound SVELON® 855B**  
**Non-target screening of the migrate for semi-volatile components**

We were appointed with a non-target-screening of a migrate of **Lining Compound SVELON® 855B** for semi-volatile components with a molecular weight < 1000 Da and a concentration above 10 µg/kg (10 ppb).

According to your information the material is intended to be used as sealant in crown corks in contact with mineral water, lemonade, beer, wine, champagne as well as further alcoholic beverages with maximum content of 50 vol% ethanol which will be pasteurized at 68 °C for 20 min (in case of beer) and stored at ambient temperature for several months.

In order to carry out the examinations we received crown corks with the mentioned lining compound.

The test specimen were brought into contact with food simulant 50 % ethanol for 10 days at 60°C as worst case condition.

**PROCEDURE OF THE EXAMINATIONS**

The crown corks were brought into contact with food simulant 50 % ethanol for 10 days at 60°C as a worst case scenario tested by applying on a glass bottle. One crown cork was in contact with 100 ml. Subsequently the migration solution was extracted with cyclohexane/ethylacetate and the extract carefully concentrated and the internal standards were added.

The analysis of the migrate was carried out by gas chromatography with mass specific detection. Further information on the test condition is available on request.

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.

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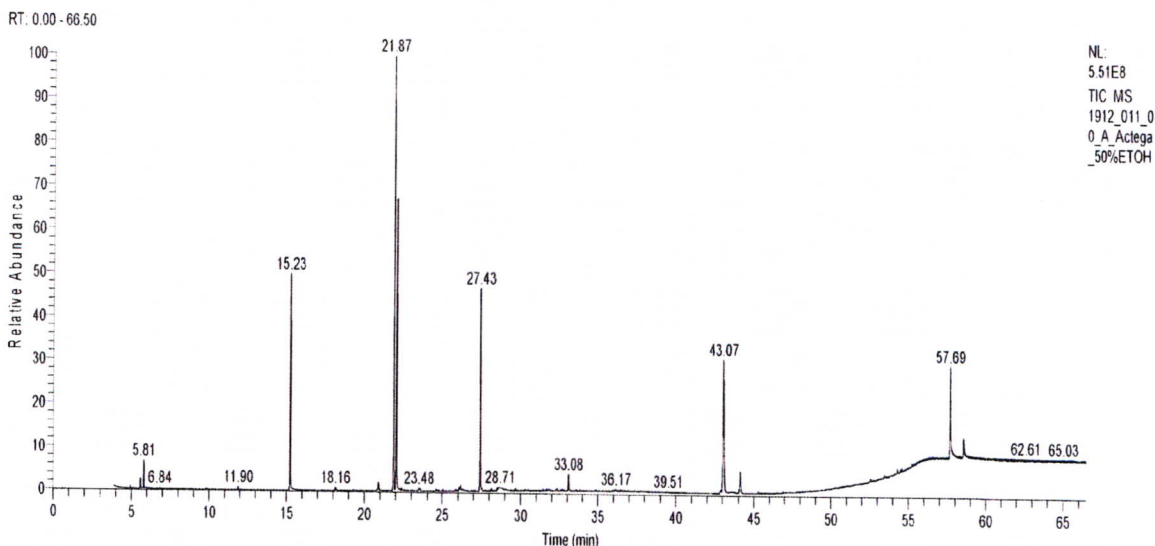
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The identification of the relevant peaks was carried out by comparison of the mass spectra with the data of a NIST library (a comprehensive data base with reference spectra). In case the consistency of the measured mass spectrum with the mass spectrum of the NIST library was above 75% based on the available information on the starting substances **Lining Compound SVELON® 855B** the identification was proven for coherence. There was no additional confirmation of the identity of the components by comparison with the respective reference substances carried out.

In case the consistency of the measured mass spectrum with the mass spectrum of the NIST library was below 75% the component was regarded as not sufficiently identified. If possible the respective component was categorised with a particular substance class.

The quantification of the components was based on the theoretical assumption that the analyte has the same response factor in the total ion current as the internal reference substances, respectively. This procedure leads to a semi-quantitative determination of the concentration expressed in mg/dm<sup>2</sup> resp. per crown cork. This concentration was transferred into a mass related concentration using a total surface area of one closure (a contact area of approx. 5 cm<sup>2</sup>) and a contact volume of 100 ml beverage.

## RESULTS OF THE EXAMINATIONS



Picture 1: GC/MS chromatogram (TIC): 50 % ethanol, 10 days at 60°C

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.

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RT (min)	Identity	Concentration [µg/kg] estimated values	Remark
15.23	Tridecane (ISTD1)	(100)	internal reference standard
21.87	Butylated Hydroxytoluene (BHT)	190	SML = 3 mg/kg
22.05	Tert-butyl-4-hydroxyanisol (ISTD 2)	(100)	internal reference standard
27.43	3,5-di tert butyl-4-hydroxy acetophenone	64	degradation product, antioxidant
43.07	2-Ethylhexyldiphenylphosphate (ISTD3)	(100)	internal reference standard
57.69	Tris(2,4-di-tert-butylphenyl) phosphite	46	listed, no SML

## EVALUATION

Based on a surface area/mass ratio of 1 crown cork /100 ml food all peaks with a semi-quantitatively estimated concentration of  $\geq 10 \mu\text{g/kg}$  were identified as far as possible with the applied analytical technique.

According to the applied analytical screening of the migrate of **Lining Compound SVELON® 855B** into 95 % ethanol there are three components present in semi-quantitatively estimated concentrations exceeding the relevant concentration of  $10 \mu\text{g/kg}$ .

Under applied test conditions the calculated sum of the concentrations of the migratable substances is  $300 \mu\text{g/kg}$  food.

The detected degradation product of listed antioxidants is not completely toxicologically evaluated. This substance group is not classified as genotoxic and can be classified in Cramer Class III. Therefore according to TTC concept an exposition up to  $90 \mu\text{g/person/day}$  will cause no reason for concern. Considering the exposure of this substances calculate with e.g. database "Matrix Calculation Tool" the exposition will be below  $90 \mu\text{g/person/day}$ .

No other substances in concentrations above  $10 \mu\text{g/kg}$  were detectable in the migrate under above mentioned analytical conditions.

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.

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Under the applied testing conditions **Lining Compound SVELON® 855B** does not contain detectable semi-volatile components migrating in food simulant 50 % ethanol in concentrations which may give reason for health concerns or which would interfere with compliance with requirements according to Art. 3 of Regulation (EC) No. 1935/2004 in conjunction with Regulation (EG) No 10/2011.

EUROFINS INSTITUT NEHRING GmbH

  
Dr. Britta Steinhaus  
Analytical Service Manager

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.

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2017-01-13  
page 1 of 7

Your ref.

Dr. Stüber/Dec. 21, 2016

Our ref./document

STWC10-017

telephone

0531-23899-0

*Translation of our test report STWC09-017 of January 13, 2017  
Amendment of our test report WJWC02-094 of October 9, 2014*

### Examination of Lining Compound SVELOX® 8500

With your above quoted letter you appointed us with the evaluation of **Lining Compound SVELOX® 8500** with regard to legal requirements for food contact materials.

According to your information the material is intended to be used as sealant in crown corks for mineral water, lemonade, beer, wine, champagne as well as further alcoholic beverages with maximum 50 vol% ethanol which will be pasteurised.

In order to carry out the examinations we received sheets of the above mentioned lining compound and crown corks with the lining compound.

The test specimens were brought into contact with aqueous solvents under test conditions which are suitable to simulate the influence of foodstuff.

The conditions for testing were applied in accordance with Regulation (EU) No 10/2011, which is valid for plastic food contact materials and articles.

In applying 21 CFR 175.300 of the US FDA Regulations, the extraction into 8 % ethanol and dist. water was determined.

### PROCEDURE OF THE EXAMINATIONS

#### 1. Evaluation of the lining compound composition

The composition of **Lining Compound SVELOX® 8500** was disclosed to the testing laboratory. The composition has been checked with regard to possible restrictions for the use of the applied starting substances for food contact applications. The evaluation of the compositional data covered all starting substances for which the chemical identity was disclosed to the testing laboratory.

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.

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For each substance it was checked whether the substance is evaluated for food contact applications according to the requirements of the European Food Safety Authority (EFSA). The evaluations are mentioned for instance in the Food Contact Materials Database of the EU Commission, DG Sanco, Regulation (EU) No 10/2011 as well as Regulation (EU) No 1282/2011, Regulation (EU) No 321/2011, Regulation (EU) No 202/2014, Regulation (EU) No 2015/174, Regulation (EU) No 2016/1416 and 21 CFR 177.1210 of the US FDA Regulations. Based on the results of the composition evaluation the required tests for specific migration and residual monomer contents in the lining compound have been selected.

## 2. Overall migration

The overall migration data were determined as dry residues of the migrates of one crown cork coming into contact with 100 ml simulants. The organic components of the dry residue were determined as their chloroform soluble parts according to the requirements of 21 CFR 175.300.

The crown corks were applied onto glass bottles which were filled with the simulants. The overall migration data were determined as dry residues of the migrates of the crown corks.

## 3. Analysis of the migrates

Each substance was analysed with the simulant which is regarded as the strictest migration solution due to the chemical and/or physical properties of the resp. substance.

The migrates of the lining compound were analysed for octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate and white mineral oil (paraffinic).

The examination for octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate was carried out by RP-HPLC with UV-detection.

With the crown corks the determination of the specific migration of sodium sulfite determined as sulfurous acid (SO<sub>2</sub>) was carried out by titration.

The examination of the specific migration of white mineral oil, paraffinic (PM-Ref. No 95883) was not carried out. Instead the overall migration under conditions of specific migration was examined and the residue was determined gravimetrically because the substances are not volatile.

## 4. Extraction test of the lining compound

The DMAA extract of the lining compound was analysed for residual 1,3-butadiene by headspace gaschromatography and mass specific detection.

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## 5. Sensory evaluation

The lining compound was brought into contact with the flavour sensitive test solutions tap water and mineral water. The contact was carried out after storage for 10 d 40 °C and a ratio of 1 crown cork : 200 ml. The sensory evaluation was carried out as pairwise comparative test by a taste panel with particular experience. As blank we used tap water and mineral water which had not been in contact with the lining compound. The evaluation was carried out in accordance with DIN 10 955 (German Institute for Standardisation).

## RESULTS OF THE EXAMINATIONS

### 1. Evaluation of the lining compound composition

According to the results of our evaluation all starting substances used for manufacturing the **Lining Compound SVELOX® 8500** are evaluated according to the requirements of the EFSA and are permitted according to Regulation (EU) No 10/2011, amended by Regulation (EU) No 1282/2011 Regulation (EU) No 321/2011, Regulation (EU) No 1183/2012, Regulation (EU) No 202/2014, Regulation (EU) No 2015/174 as well as Regulation (EU) No 2016/1416, for the use in contact with foods.

All of the starting substances are permitted according to 21 CFR 177.1210 of the US FDA Regulations.

According to the result of our composition check the following starting substances for which restrictions have been expressed are used:

Starting substance	PM Ref Nr.	Restriction	Remark
Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	68320	SML = 6 mg/kg	-
2,4-bis(octylthio)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	40000	SML = 5 mg/kg	-
2,6-di-tert-butyl-p-cresol (BHT)	46640	SML = 3 mg/kg	-
Additive A*	-	SML = 0.6 mg/kg	-
Sodium sulfite	86960	SML(T) = 10 mg/kg determined as SO <sub>2</sub>	-
White mineral oil (paraffinic)	95883	SML = 60 mg/kg	-
1,3-butadiene	13630	QM = 1 mg/kg FP	-

\*The identity of the component is known to the testing laboratory. It is kept under confidentiality by the raw material supplier.

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstituts weder vollständig noch auszugsweise veröffentlicht werden.

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The specific migration of 2,4-bis(octylthio)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine, 2,6-di-tert-butyl-p-cresol (BHT) and Additive A\* have not been examined because taking the amounts into account even under conditions of total migration the specific migration limits will not be exceeded.

According to the results of our evaluation 2,6-di-tert-butyl-p-cresol (BHT) and sodium sulfite are used as dual use additives in the composition.

## 2. Overall migration

Simulants	t/T conditions	Dry residue of migrates mg/cc*	Chloroform soluble parts of dry residue mg/cc*
3 % acetic acid	10 d 40 °C	0.6	-
20 % ethanol	10 d 40 °C	1.1	-
50 % ethanol	10 d 40 °C	1.2	-

\*cc = crown cork

Simulants	t/T conditions	Dry residue of migrates mg/cc*	Chloroform soluble parts of dry residue mg/cc*
dist. water	100 °C, cool down to 38 °C	0.4	0.4
8 % ethanol	2 h 65 °C	0.8	0.7

\*cc = crown cork

## 3. Analysis of the migrates

	Simulants	t/T conditions	Results
Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	50 % ethanol	10 d 60 °C	n.d. (< 0.1 mg/cc*)
Sodium sulfite as SO <sub>2</sub>	3 % acetic acid 50 % ethanol	10 d 60 °C 10 d 60 °C	n.d. (< 0.3 mg/cc*) n.d. (< 0.3 mg/cc*)
White mineral oil	50 % ethanol	10 d 60 °C	3.4 mg/cc*

n.d. = not detectable

\*cc = crown cork

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4. Extraction test of the lining compound

DMAA extraction, headspace GC-MS

	Result
1.3-butadiene	n.d. (< 0.001 mg/cc*)

n.d. = not detectable

\*cc = crown cork

5. Sensory evaluation

Simulant t/T conditions	Surface/volume ratio	Appearance	Odour	Flavour
Tap water 10 d 40 °C	1 crown cork : 200 ml	0	0	0.5
Mineral water 10 d 40 °C	1 crown cork : 200 ml	0	0	0

0 = no deviation detectable

1 = deviation slightly detectable

2 = slight deviation

3 = considerable deviation

4 = strong deviation

EVALUATION1. Evaluation of the lining gasket composition

**Lining Compound SVELOX® 8500** contains 7 starting substances for which restrictions have to be regarded when the sealant is used in contact with foodstuffs. All starting substances are evaluated according to EFSA requirements for food contact applications.

2. Overall migration

Assuming that the lining compound is used for a crown cork or aluminium screw cap with a food contact surface of 5 cm<sup>2</sup> applied onto a 200 ml glass bottle with a total internal surface of approx. 195 cm<sup>2</sup> the following overall migration data in mg/dm<sup>2</sup> can be calculated:

Simulants	t/T conditions	Overall migration mg/dm <sup>2</sup>	Chloroform soluble parts of dry residue mg/dm <sup>2</sup>
3 % acetic acid	10 d 40 °C	0.02	-
20 % ethanol	10 d 40 °C	0.03	-
50 % ethanol	10 d 40 °C	0.03	-

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Assuming that the lining compound is used for a twist crown applied onto a 200 ml glass bottle with a food contact surface of approx. 5 cm<sup>2</sup> the following overall migration data in mg/l (ppm) can be calculated:

Simulants	t/T conditions	Overall migration mg/l	Chloroform soluble parts of dry residue mg/l
dist. water	100 °C, cool down to 38 °C	2.0	2.0
8 % ethanol	2 h 65 °C	4.0	3.5

Taking the small amount of lining compound of approx. 5 cm<sup>2</sup> applied to one twist crown for a 200 ml bottle into account the overall migration data are below the limit of 10 mg/dm<sup>2</sup> according to Regulation (EU) No 10/2011.

They are also lower than the limits mentioned in 21 CFR 177.1210 of the US FDA Regulations concerning lining compound.

### 3. Analysis of the migrates

The analysis of the migrates of the crown corks showed no specific migration of octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate and sodium sulphite which give reason for concerns.

Based on the application of one crown cork on a 200 ml bottle the test result of the gravimetric determination is far below the specific limit for white mineral oil (paraffinic) of 60 mg/kg.

### 4. Extraction test of the lining compound

The examination of the lining compound did not show detectable residues of 1,3-butadiene.

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## 5. Sensory evaluation

Under test conditions the lining compound does not deliver any opacifying or colouring agents to the test solution applied. There is no influence of off-odour and off-flavours in the test solution. Consequently, on account of the sensory evaluation no off-odour and off-flavour changes have to be expected which would adversely affect aqueous, acidic or low alcoholic food.

With respect to the examinations carried out, the **Lining Compound SVELOX® 8500** as compound material for crown corks for mineral water, lemonade, beer, wine, champagne as well as further alcoholic beverages with maximum 50 vol% ethanol which will be pasteurised, was evaluated as follows:

Under the applied test conditions with different simulants there was no overall migration detectable which would give reasons for concern. Taking the small compound surface into account which will come into direct food contact the values being obtained are below the limit of 10 mg/dm<sup>2</sup> according to Regulation (EU) No 10/2011.

The examination of the lining compound showed that there are no reasons to assume migration of health-hazardous parts from the sealant into food.

Under the conditions of intentional or foreseeable use no adverse effect from the lining gasket on odour and/or flavour is to be expected.

Assuming the application as a constituent of a food contact material according to § 2 no. 6 of the Lebensmittel- und Futtermittelgesetzbuch (LFGB) (German Law Book on Foodstuff and Feeds) the **Lining Compound SVELOX® 8500** is in compliance with the requirement according to Art. 3 Regulation (EC) No. 1935/2004 as well as § 30 and § 31 (1) LFGB in connection with Regulation (EU) No 10/2011.

The lining compound complies with requirements according to 21 CFR 177.1210 of the US FDA Regulations.

INSTITUT NEHRING GmbH

Dr. Ulrich Nehring  
General Manager



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