



26 May 2011

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Your Reference:
26.04.2011 / AK

Our Reference:
2011L17219

Examination of SA 291/25 mod. Compound

We have been appointed by your letter dated 2011-04-26 to analyse and to assess the compound SA 291/25 mod. with respect to current food legislation.

Product data:

Sample: SA 291/25 mod. White Compound
Intended use: According to the submitted data the product is used as a sealing compound in metal lids covering glass jars for food.
Documents: Formulation of the compound

Analytic

Overall migration

The global migration has been determined by our chemical analysis. For this the samples were exposed to aqueous and non-aqueous solvents under test conditions which are suitable to simulate the influence of foodstuff. Test conditions were selected according to Council Directive 85/572/EEC and Commission Directive 97/48/EC and as well to Regulation (EC) No. 10/2011.

Analysis of migrates

The migrates were analyzed under test conditions applicable for the overall migration. The following substances, for which a specific migration limit (SML) exists, have been analyzed: plasticizer, vinyl chloride, additives

Sensory evaluation

The test samples were sensorial examined by storage in tap water (1 h 100 °C + 10 d 40 °C). As blank tap water was used which had not been in contact with the gasket material.





Results of the examinations

Overall migration

Simulant	Test conditions (Time/Temperature)	Dry Residue of Migrates in mg/dm ²
A) 10 % Ethanol	1 h 100 °C + 10 d 40 °C	21
B) 3 % Acetic Acid	1 h 100 °C + 10 d 40 °C	18
D1) 50 % Ethanol	1 h 100 °C + 10 d 40 °C	49
D2) Olive oil	1 h 100 °C + 10 d 40 °C	220

Specific migration

a) Plasticizer*

Simulant/Substance	Plasticizer 1		Plasticizer 2		Plasticizer 3	
	Result (mg/dm ²)	LoD** (mg/dm ²)	Result (mg/dm ²)	LoD** (mg/dm ²)	Result (mg/dm ²)	LoD** (mg/dm ²)
A) 10 % Ethanol	0.5	0.05	16	0.02	< 0.01	0.01
B) 3 % Acetic Acid	1.7	0.05	9.1	0.02	< 0.01	0.01
D1) 50 % Ethanol	5.6	0.05	21	0.02	18	0.01
D2) Olive oil	22	0.05	103	0.02	80	0.01

* The identity is known to the testing institute. It is subject to a secrecy agreement with the raw material supplier.

** LoD = Limit of Detection

ESBO, not present in the formulation, was also not detectable in the simulants (NG = 1 mg/dm²)

b) Additive

Simulant/Substance	Barium	
	Result (mg/dm ²)	LoD (mg/dm ²)
A) Dist. Water	< 0.1	0.1
B) 3 % Acetic acid	< 0.1	0.1
C) 10 % Ethanol	< 0.1	0.1
D) Isooctane	< 0.1	0.1

c) Vinyl chloride (DMAA-Extraction)

Substance	Result mg/dm ²	LoD (mg/dm ²)
Vinyl chloride	< 0.015	0.015

Sensory evaluation

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

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

Assessment

Overall migration

For calculation of the overall migration in mg/kg following is assumed:

Lid size: 63 mm diameter

Glass jar volume: 250 ml

Contact area of gasket material: 5.17 cm²

Based on this example the following values for overall migration can be calculated:

Simulant	Test conditions (Time/Temperature)	Dry Residue of Migrates in mg/kg
A) 10 % Ethanol	1 h 100 °C + 10 d 40 °C	4.3
B) 3 % Acetic Acid	1 h 100 °C + 10 d 40 °C	3,7
D1) 50 % Ethanol	1 h 100 °C + 10 d 40 °C	10,1
D2) Olive oil	1 h 100 °C + 10 d 40 °C	45

Under the test conditions previously described, with the used aqueous and non-aqueous simulants there was no overall migration which would give reason for concern. Considering the small amount of sealing compound which gets possibly into direct food contact (surface/volume ratio) the obtained values are below the limit of 60 mg/kg set in the directive 2002/72/EC, recently changed by the Regulation (EC) No. 975/2009 as well below the limit of Regulation (EC) Nr. 10/2011, which replaces Directive 2002/72/EC. A material or article should be deemed in compliance with the directive, if it exceeds the overall migration limit by an amount not greater than the analytical tolerance of 20 mg/kg or 3 mg/dm² in migration tests using rectified olive oil or substitutes or 12 mg/kg or 2 mg/dm² in migration tests using the other simulants referred to in Directive 82/711/EEC and 85/572/EEC, respectively.

When applied for fatty foods, an increased migration of the plasticizers into the foods may occur under conditions of large surface/volume ratios. Therefore this assessment does not relieve the user of compound SA 291/25 mod. to accomplish its own migration investigations since surface/volume ratios selected for the final product have a significant impact on the results of the migration analysis.



Further exemplary calculations for the overall migration with olive oil using different surface/volume ratios are given below (according to Directive 2002/72/EC the analytical tolerance of +/- 20 mg/kg is applicable):

Overall migration in olive oil (mg/dm ²)	Lid Diameter (mm)	Contact area (cm ²)	Volume (ml)	Calculated Migration (mg/kg)
220	82	6.93	700	22
220	82	6.93	333	46
220	82	6.93	250	60
220	82	6.93	100	152
220	63	5.17	700	16
220	63	5.17	333	34
220	63	5.17	250	45
220	63	5.17	100	114
220	53	4.22	700	13
220	53	4.22	333	28
220	53	4.22	250	37
220	53	4.22	100	92

Analysis of the migrates

The analysis of the migrates showed no specific migration of vinyl chloride. The Barium content was also below its specific limit of 1 mg/kg. The amount of plasticizer determined in the simulants is below the overall migration value and below the specific migration limit. Based on the above selected surface/volume ratios (250 ml und 5.17 cm²) following migration values result for the used plasticizer:

Simulant/Substance	Plasticizer 1 (mg/kg)	Plasticizer 2 (mg/kg)	Plasticizer 3 (mg/kg)
A) 10 % Ethanol	0.17	3.3	< 0.01
B) 3 % Acetic Acid	0.35	1.9	< 0.01
D1) 50 % Ethanol	1.2	4.3	3.7
D2) Olive oil	4.5	21	16.5

ESBO, not present in the formulation, was also not detectable in the simulants (NG = 1 mg/dm²)

Sensory evaluation

The sensorial evaluation showed no deviation with regard to appearance, odour and flavour. The assessment was carried out in accordance to DIN 10955. The stronger odour is not untypically for samples like the present. Taking into account real conditions as above described, the effect will be diluted.



General Assessment

Due to the evaluation based on the submitted documents (formulation) and the composition derived from it, 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 use conditions the product specified in this report does thereafter not add components to food in quantities that are suitable to endanger the human health, to cause an untenable change of the composition or an impairment of the organoleptic characteristics of the food.

The compound SA 291/25 mod. complies with the requirements of the § 31 paragraph 1 of the LFGB and is eligible for the manufacture of commodities as defined by § 5 paragraph 1 No. 1.

This report exclusively refers to the analyzed 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. Names and structures of the used components of the formulation are known to us, the testing laboratory, and can be inspected on request by national control authorities.

References

- Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004
- Regulation (EC) No. 10/2011 of 14 January 2011
- Commission Directive 2002/72/EC of 6 August 2002
- Commission Directive 2007/19/EC of 30 March 2007
- Commission Regulation (EC) No. 975/2009 of 19 October 2009
- Commission Directive (85/572/EEC) of 19 December 1985
- Commission Directive 97/48/EC of 29 July 1997
- LFGB - German Code of Law for Food and Feeds
- DIN 10995, issued June 2004

Dietikon, 26 May 2011

SQTS - SWISS QUALITY TESTING SERVICES

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