

Customer details: Flexitallic Ltd
Scandinavia Mill
Hunsworth Lane
Cleckheaton
West Yorkshire
BD19 4LN

SATRA reference: CHM0253181/1701/EN
/Final

Your reference:

Date of report: 6th March 2017

Samples received: 16th January 2017

Date(s) work carried out: 20th January to 6th March 2017

For the attention of: Stuart Shaw

TECHNICAL REPORT

Subject: Overall and specific migration testing in accordance with BS EN 1186:2002 and commission regulations 10/2011 on samples described as Sigma 511.

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Please note uncertainty of measurement has not been applied to the results in this report. SATRA uncertainty of measurement values are available on request.

Report signed by: Emma Norris
Position: Chemical Technologist
Department: Chemical & Analytical Technology

WORK REQUESTED:

Samples described as Sigma 511 were received on the 16th January 2017 for assessment in accordance with the overall migration limit requirements of Commission Regulation No. 10/2011.

The specific migration limit testing for tetrafluoroethylene and hexafluoropropylene and metals in sunflower oil was carried out by an external laboratory and reported under their reference AC/REP/141050/20/1.

CONCLUSIONS:

When tested in accordance with BS EN 1186-3: 2002 the samples described as Sigma 511 were found to meet with the overall migration limit requirements when assessed against 10% ethanol, 3% acetic acid, 20% ethanol and 50% ethanol for 2 hours under reflux.

The samples described as Sigma 511 were found to be unsuitable for testing against simulant D2; therefore the alternative simulants (Iso-octane and 95% Ethanol) were tested against. The samples were found to meet with the overall migration limit requirements when assessed against alternative simulants iso-octane for 1.5 hours at 60°C and 95% ethanol for 3.5 hours at 60°C.

The specific migration limits for metals were assessed after extraction in 10% ethanol, 3% acetic acid, 20% ethanol and 50% ethanol for 2 hours under reflux and were found to meet with the requirements in Commission Regulation (EU) No 10/2011, Annex II. The specific migration limits for metals were assessed after extraction in sunflower oil for 2 hours 100°C and were found to meet with the requirements in Commission Regulation (EU) No 10/2011, Annex II.

The specific migration limit testing for tetrafluoroethylene and hexafluoropropylene was assessed after extraction in 10% ethanol, 3% acetic acid, 20% ethanol, 50% ethanol and sunflower oil for 2 hours at 100°C and the samples were found to meet the requirements.

Results are given in the following tables.

TESTING REQUIRED:

- BS EN 1186 part 3: 2002 Materials and articles in contact with foodstuffs – Plastics Test methods for overall migration into aqueous food simulants by total immersion for 2 hours under reflux
 - 10% Ethanol (simulant A Commission Regulation No. 10/2011)
 - 3% Acetic Acid (simulant B in Commission Regulation No. 10/2011)
 - 20% Ethanol (simulant C in Commission Regulation No. 10/2011)
 - 50% Ethanol (simulant D1 in Commission Regulation No. 10/2011)

- #SATRA SOP CAT 035-determination of total migration into food contact materials using simulant D2

Note: The blank specimen extract contained interferences which resulted in this method being unsuitable for these specific samples. Therefore, testing was carried out using the alternative simulants below.

- BS EN 1186 part 14: 2002 Test methods for 'substitute tests' for overall migration from plastics intended to come into contact with fatty foodstuffs using test media iso-octane and 95% ethanol by total immersion.
 - 95% Ethanol for 3.5 hours at 60°C
 - Iso-octane for 1.5 hours at 60°C
- #SATRA SOP CAT-015 – Migration of metal elements (Ba, Co, Cu, Fe, Li, Mn, Zn) into food simulants (A-D1) 2 hours under reflux . Quantification by ICP- OES.
- #TES-AC-812 (determination by SPME GC/MS) Migration of metal elements (Ba, Co, Cu, Fe, Li, Mn, Zn) into food simulant D2 (vegetable oil*) 2 hours at 100°C (Performed by an external laboratory)
- #TES-AC-812; Based on EN 1186: 2002 Materials and articles in contact with foodstuffs – Plastics Test methods for overall migration into aqueous food simulants followed by analysis of specific migration of tetrafluoroethylene (TFE) and hexafluoropropylene (HFP). (Performed by an external laboratory)
 - Simulant A - 10% ethanol for 2 hours at 100°C
 - Simulant B - 3% acetic acid for 2 hours at 100°C
 - Simulant C – 20% ethanol for 2 hours at 100°C
 - Simulant D1 – 50% ethanol for 2 hours at 100°C
 - Simulant D2 – vegetable oil* for 2 hours at 100°C

*Note: Sunflower oil was used as an alternative to rectified olive oil – “reference simulant D”. The sunflower oil used has characteristics in accordance with those specified in Annex A of BS EN 1186-1: 2002.

RESULTS AND REQUIREMENTS:

Migration into aqueous food simulants by total immersion

Sample	Test Method	Global migration (mg/dm ²)		Mean Global migration (mg/dm ²)	Pass/Fail
Sigma 511	BS EN 1186-3 (10% ethanol)	A	4.4	4.7	Pass
		B	4.8		
		C	4.9		
	BS EN 1186-3 (3% acetic acid)	A	10.8	8.6	Pass
		B	3.7		
		C	11.4		
	BS EN 1186-3 (20% ethanol)	A	4.3	5.2	Pass
		B	6.2		
		C	5.0		
	BS EN 1186-3 (50% ethanol)	A	5.4	4.5	Pass
		B	4.2		
		C	3.8		
Requirement	-	-	<10 mg/dm²	-	

Migration into alternative simulants by total immersion

Sample	Test Method	Global migration (mg/dm ²)		Mean Global migration (mg/dm ²)	Pass/Fail
Sigma 511	BS EN 1186-14 (95% ethanol)	A	1.9	1.8	Pass
		B	3.4		
		C	<1.0		
	BS EN 1186-14 (iso-octane)	A	< 1.0	<1.0	Pass
		B	< 1.0		
		C	< 1.0		
Requirement	-	-	<10 mg/dm²	-	

#SATRA SOP CAT-015 – Migration of metal elements (Ba, Co, Cu, Fe, Li, Mn, Zn) into food simulants. Quantification by ICP- OES.

Sample tested	Simulant	Element (mg/kg of foodstuffs)						
		Ba	Co	Cu	Fe	Li	Mn	Zn
Sigma 511	10% ethanol	<0.1	<0.05	<0.05	0.2	<0.1	0.2	< 1.0
	3% acetic acid	0.1	<0.05	<0.05	1.9	<0.1	<0.1	< 1.0
	20% ethanol	<0.1	<0.05	<0.05	1.7	<0.1	<0.1	< 1.0
	50% ethanol	<0.1	<0.05	<0.05	0.2	<0.1	0.2	< 1.0
Requirement of the Commission Regulation (EU) No 10/2011, Annex II		1	0.05	5	48	0.6	0.6	25

Results are the mean of triplicate determinations

#TES-AC-812 (determination by SPME GC/MS) Migration of metal elements (Ba, Co, Cu, Fe, Li, Mn, Zn) into food simulant D2 (vegetable oil*)

Sample tested	Simulant	Element (mg/kg of foodstuffs)						
		Ba	Co	Cu	Fe	Li	Mn	Zn
Sigma 511	Sunflower oil	0.10	<0.01	<0.02	<0.07	0.02	<0.01	0.02
Requirement of the Commission Regulation (EU) No 10/2011, Annex II		1	0.05	5	48	0.6	0.6	25

Results are the mean of triplicate determinations

#Specific migration into aqueous food simulants

Sample	Simulant	Specific migrant	Specific migration (mg/kg)		Specific migration limit (mg/kg)	Pass/Fail			
			A	B					
Sigma 511	10% ethanol	TFE (tetrafluoroethylene)	A	<0.01	0.05	Pass			
			B	<0.01					
			C	<0.01					
	3% acetic acid		A	<0.01		0.05	Pass		
			B	<0.01					
			C	<0.01					
	20% ethanol		A	<0.01			0.05	Pass	
			B	<0.01					
			C	<0.01					
	50% ethanol		A	<0.01				0.05	Pass
			B	<0.01					
			C	<0.01					
Sunflower oil	A	<0.01	0.05	Pass					
	B	<0.01							
	C	<0.01							
Sigma 511	10% ethanol	HFP (hexafluoropropylene)		A	<0.01	0.01			Pass
				B	<0.01				
				C	<0.01				
	3% acetic acid			A	<0.01		0.01		Pass
				B	<0.01				
				C	<0.01				
	20% ethanol			A	<0.01			0.01	Pass
				B	<0.01				
				C	<0.01				
	50% ethanol		A	<0.01	0.01				Pass
			B	<0.01					
			C	<0.01					
Sunflower oil	A	<0.01	0.01	Pass					
	B	<0.01							
	C	<0.01							

Concerning specific migration results, in accordance with commission regulation 10/2011 the specific gravity of all simulants conventionally is assumed to be '1'. 1kg of food simulant therefore is taken to occupy the volume of 1L. The SML is set with the assumption that 6.0dm² of surface area comes into contact with 1kg of food. Results are adjusted for 6.0dm²/kg.

APPENDICES:

The samples described as Sigma 511 are suitable for contact with the following food categories of foodstuffs as listed in 10/2011 Annex III, table 2.

Reference number	Description of foodstuffs
01	Beverages
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than or equal to 6% vol: A. Clear drinks: Water, ciders, clear fruit or vegetable juices of normal strength or concentrated, fruit nectars, lemonades, syrups, bitters, infusions, coffee, tea, beers, soft drinks, energy drinks and the like, flavoured water, liquid coffee extract B. Cloudy drinks: Juices and nectars and soft drinks containing fruit pulp, musts containing fruit pulp, liquid chocolate
01.02	Alcoholic beverages of an alcoholic strength of between 6% vol and 20%.
01.03	Alcoholic beverages of an alcoholic strength above 20 % and all cream liquors
02	Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares
02.05	Pastry, biscuits, cakes, bread, and other bakers'wares, dry: A. With fatty substances on the surface
02.06	Pastry, cakes, bread, dough and other bakers'wares, fresh: A. With fatty substances on the surface
03	Chocolate, sugar and products thereof
	Confectionery products
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes
03.02	Confectionery products: A. In solid form: I. With fatty substances on the surface B. In paste form: I. With fatty substances on the surface II. Moist
03.03	Sugar and sugar products B. Molasses, sugar syrups, honey and the like
04	Fruit, vegetables and products thereof
04.01	Whole fruit, fresh or chilled, unpeeled

04.02	<p>Processed fruit:</p> <ul style="list-style-type: none"> B. Fruit in the form of puree, preserves, pastes or in its own juice or in sugar syrup (jams, compote, and similar products) C. Fruit preserved in a liquid medium: <ul style="list-style-type: none"> I. In an oily medium II. In an alcoholic medium
04.03	<p>Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others):</p> <ul style="list-style-type: none"> C. In paste or cream form
04.04	<p>Whole vegetables, fresh or chilled</p>
04.05	<p>Processed vegetables:</p> <ul style="list-style-type: none"> B. Fresh vegetables, peeled or cut C. Vegetables in the form of puree, preserves, pastes or in its own juice (including pickled and in brine) D. Preserved vegetables: <ul style="list-style-type: none"> I. In an oily medium II. In an alcoholic medium
05	<p>Fats and oils</p>
05.01	<p>Animals and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, resolidified butter)</p>
05.02	<p>Margarine, butter and other fats and oils made from water emulsions in oil</p>
06	<p>Animal products and eggs</p>
06.01	<p>Fish:</p> <ul style="list-style-type: none"> A. Fresh, chilled, processed, salted or smoked including fish eggs B. Preserved fish: <ul style="list-style-type: none"> I. In an oily medium II. In an aqueous medium
06.02	<p>Crustaceans and molluscs (including oysters, mussels, snails):</p> <ul style="list-style-type: none"> A. Fresh within the shell B. Shell removed, processed, preserved or cooked with the shell <ul style="list-style-type: none"> I. In an oily medium II. In an aqueous medium
06.03	<p>Meat of all zoological species (including poultry and game):</p> <ul style="list-style-type: none"> A. Fresh, chilled, salted, smoked B. Processed meat products (such as ham, salami, bacon, sausages, and other) or in the form of paste, creams C. Marinated meat products in an oily medium
06.04	<p>Preserved meat:</p>

06.05	<ul style="list-style-type: none"> A. In an fatty or oily medium B. In an aqueous medium <p>Whole eggs, egg yolk, egg white</p> <ul style="list-style-type: none"> B. Liquid and cooked
07	<p>Milk products</p> <p>07.01 Milk</p> <ul style="list-style-type: none"> A. Milk and milk based drinks whole, partly dried and skimmed or partly skimmed <p>07.02 Fermented milk such as yoghurt, buttermilk and similar products</p> <p>07.03 Cream and sour cream</p> <p>07.04 Cheeses:</p> <ul style="list-style-type: none"> B. Natural cheese without rind or with edible rind (gouda, camembert, and the like) and melting cheese C. Processed cheese (soft cheese, cottage cheese and similar) D. Preserved cheese: <ul style="list-style-type: none"> I. In an oily medium II. In an aqueous medium (feta, mozzarella and similar)
08	<p>Miscellaneous Products</p> <p>08.01 Vinegar</p> <p>08.02 Fried or roasted foods:</p> <ul style="list-style-type: none"> A. Fried potatoes, fritters and the like B. Of animal origin <p>08.03 Preparations for soups, broths, sauces, in liquid, solid or powder form (extracts, concentrates); homogenised composite food preparations, prepared dishes including yeast and raising agents:</p> <ul style="list-style-type: none"> A. Powdered or dried: <ul style="list-style-type: none"> I. With fatty character B. any other form than powdered or dried: <ul style="list-style-type: none"> I. With fatty character II. Other <p>08.04 Sauces:</p> <ul style="list-style-type: none"> A. With aqueous character B. With fatty character e.g. mayonnaise, sauces derived from mayonnaise, salad creams and other oil/water mixtures e.g. coconut based sauces <p>08.05 Mustard (except powdered mustard)</p> <p>08.06 Sandwiches, toasted bread pizza and the like containing any kind of foodstuff</p> <ul style="list-style-type: none"> A. With fatty substances on the surface <p>08.07 Ice creams</p>

08.08	Dried foods: A. With fatty substances on the surface
08.10	Concentrated extracts of an alcoholic strength equal to or exceeding 6% vol.
08.11	Cocoa: B. Cocoa paste
08.15	Spices and seasoning in oily medium such as pesto, curry paste



Sample described as Sigma 511

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Issue Date: 1st October 2009