

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

SATRA reference: CHM0243989/1612/EN

Your reference:

Date of report: 5<sup>th</sup> April 2016

Samples received: 4<sup>th</sup> December 2015  
and 4<sup>th</sup> February 2016

For the attention of: Steve Woolfenden

Date(s) work carried out: 16<sup>th</sup> February to 10<sup>th</sup>  
March 2016

## 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 500.

### Conditions of Issue:

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Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

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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 500 were received on the 4<sup>th</sup> December 2015 and 4<sup>th</sup> February 2016 for assessment in accordance with the overall migration limit requirements of Commission Regulation No. 10/2011.

The overall migration limit testing against vegetable oil and specific migration limit testing was carried out by an external laboratory and reported under their references AC/REP/137555/144 and AC/REP/138188/133.

Results are also applicable to SIGMA 501 (unpigmented variant).

## CONCLUSIONS:

When tested in accordance with BS EN 1186-3: 2002 the samples described as SIGMA 500 were found to meet with the overall migration limit requirements when assessed against 10% ethanol, 50% ethanol and 3% acetic acid for 2 hours under reflux.

The samples described as SIGMA 500 were found to meet with the overall migration limit requirements when assessed against sunflower oil for 2 hours at 100°C.

The specific migration limits for metals were assessed after extraction in 3% acetic acid for 2 hours at 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 were assessed after extraction in 3% acetic acid, 10% ethanol, 50% ethanol and sunflower oil and 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)
  - 50% Ethanol (simulant D1 in Commission Regulation No. 10/2011)
- TES-AC-500; Based on EN 1186 part 2: 2002 Materials and articles in contact with foodstuffs – Plastics Test methods for overall migration into olive oil by total immersion for 2 hours at 100°C. (Performed by an external laboratory)
  - Vegetable oil\* (simulant D2 in Commission Regulation No. 10/2011)
- ≠SATRA SOP CAT-015 – Migration of metal elements (Ba, Co, Cu, Fe, Li, Mn, Zn) into food simulants. Quantification by ICP- OES.
- ≠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 reflux
  - Simulant B – 3% acetic acid for 2 hours at reflux
  - Simulant D1 – 50% Ethanol for 2 hours at reflux
  - 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 <sup>2</sup> )		Mean Global migration (mg/dm <sup>2</sup> )	Pass/Fail
		A	B		
SIGMA 500	BS EN 1186-3 (10% Ethanol)	A	8.2	4.6	Pass
		B	1.5		
		C	4.1		
SIGMA 500	BS EN 1186-3 (3% Acetic acid)*	A	6.7	4.0	Pass
		B	1.4		
		C	3.8		
<b>Requirement</b>	-	-	-	<b>&lt;10 mg/dm<sup>2</sup></b>	-

Tested and reported under reference CHM0240815.

Sample	Test Method	Global migration (mg/dm <sup>2</sup> )		Mean Global migration (mg/dm <sup>2</sup> )	Pass/Fail
		A	B		
SIGMA 500	BS EN 1186-3 (50% Ethanol)	A	< 1.0	< 1.0	Pass
		B	1.1		
		C	< 1.0		
<b>Requirement</b>	-	-	-	<b>&lt;10 mg/dm<sup>2</sup></b>	-

### Migration into vegetable oil by total immersion

Sample	Test Method	Global migration (mg/dm <sup>2</sup> )		Mean Global migration (mg/dm <sup>2</sup> )	Pass/Fail
		A	B		
SIGMA 500	TES-AC-500/ BS EN 1186 (sunflower oil)*	A	< 1.0	<1.0	Pass
		B	< 1.0		
		C	< 1.0		
<b>Requirement</b>	-	-	-	<b>&lt;10 mg/dm<sup>2</sup></b>	-

Tested and reported under reference CHM0240815, testing was carried out by an external laboratory.

#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 500	3% acetic acid	<0.1	<0.05	<0.05	<0.1	<0.1	<0.1	< 1.0
<b>Requirement of the Commission Regulation (EU) No 10/2011, Annex II</b>		<b>1</b>	<b>0.05</b>	<b>5</b>	<b>48</b>	<b>0.6</b>	<b>0.6</b>	<b>25</b>

Tested and reported under reference CHM0240815, 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		
SIGMA 500	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				
	Sunflower oil	TFE (tetrafluoroethylene)	A	<0.01	0.05	Pass		
			B	<0.01				
			C	<0.01				
	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						
Sunflower oil	HFP (hexafluoropropylene)	A	<0.01	0.01	Pass			
		B	<0.01					
		C	<0.01					

Tested and reported under reference CHM0240815.

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 6.0dm<sup>2</sup> of surface area comes into contact with 1kg of food. Results are adjusted for 6.0dm<sup>2</sup>/kg.

Sample	Simulant	Specific migrant	Specific migration (mg/kg)	Specific migration limit (mg/kg)	Pass/Fail
SIGMA 500	50% Ethanol	TFE (tetrafluoroethylene)	A <0.01	0.05	Pass
			B <0.01		
			C <0.01		
SIGMA 500	50% Ethanol	HFP (hexafluoropropylene)	A <0.01	0.01	Pass
			B <0.01		
			C <0.01		

Testing carried out at an external laboratory and reported under AC/REP/138188/133.

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 6.0dm<sup>2</sup> of surface area comes into contact with 1kg of food. Results are adjusted for 6.0dm<sup>2</sup>/kg.

## APPENDICES:

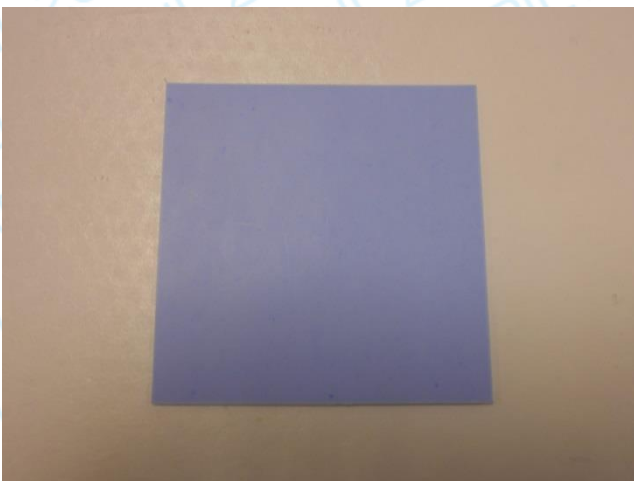
The samples described as SIGMA 500 are suitable for contact with the following food categories of foodstuffs as listed in 10/2011 Annex III, table 2.

Reference number	Description of foodstuffs
01 01.01	<b>Beverages</b> Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than or equal to 6 % vol.: B. cloudy drinks: juices and nectars and soft drinks containing fruit pulp, musts containing fruit pulp, liquid chocolate
01.03	Alcoholic beverages of an alcoholic strength above 20 % and all cream liquors
02 02.05	<b>Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares</b> 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 03.01 03.02	<b>Chocolate, sugar and products thereof confectionery products</b> Chocolate, chocolate-coated products, substitutes and products coated with substitutes  Confectionery products: A. In solid form: I. With fatty substances on the surface B. In paste form: I. With fatty substances on the surface
03.03	Sugar and sugar products B. Molasses, sugar syrups, honey and the like
04 04.01	<b>Fruit, vegetables and products thereof</b> Whole fruit fresh or chilled, unpeeled
04.02	Processed fruit: C Fruit preserved in a liquid medium: I. In an oily medium II. In an alcoholic medium
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others): C. In paste or cream form
04.04	Whole vegetables, fresh or chilled
04.05	Processed vegetables: B. Fresh vegetables, peeled or cut D. Preserved vegetables: I. In an oily medium

	II. In an alcoholic medium
05	<b>Fats and oils</b>
05.01	Animals and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, resolidified butter)
05.02	Margarine, butter and other fats and oils made from water emulsions in oil
06	<b>Animal products and eggs</b>
06.01	Fish: <ul style="list-style-type: none"> <li>A. Fresh, chilled, processed, salted or smoked including fish eggs</li> <li>B. Preserved fish: <ul style="list-style-type: none"> <li>I. In an oily medium</li> </ul> </li> </ul>
06.02	Crustaceans and molluscs (including oysters, mussels, snails): <ul style="list-style-type: none"> <li>A. Fresh within the shell</li> <li>B. Shell removed, processed, preserved or cooked with the shell <ul style="list-style-type: none"> <li>I. In an oily medium</li> </ul> </li> </ul>
06.03	Meat of all zoological species (including poultry and game): <ul style="list-style-type: none"> <li>A. Fresh, chilled, salted, smoked</li> <li>B. Processed meat products (such as ham, salami, bacon, sausages, and other) or in the form of paste, creams</li> <li>C. Marinated meat products in an oily medium</li> </ul>
06.04	Preserved meat: <ul style="list-style-type: none"> <li>A. In an fatty or oily medium</li> <li>B. In an aqueous medium</li> </ul>
06.05	Whole eggs, egg yolk, egg white <ul style="list-style-type: none"> <li>B. Liquid and cooked</li> </ul>
07	<b>Milk products</b>
07.01	Milk <ul style="list-style-type: none"> <li>A. Milk and milk based drinks whole, partly dried and skimmed or partly skimmed</li> </ul>
07.02	Fermented milk such as yoghurt, buttermilk and similar products
07.03	Cream and sour cream
07.04	Cheeses: <ul style="list-style-type: none"> <li>B. Natural cheese without rind or with edible rind (gouda, camembert, and the like) and melting cheese</li> <li>C. Processed cheese (soft cheese, cottage cheese and similar)</li> <li>D. Preserved cheese: <ul style="list-style-type: none"> <li>I. In an oily medium</li> <li>II. In an aqueous medium (feta, mozzarella and similar)</li> </ul> </li> </ul>
08	<b>Miscellaneous Products</b>
08.01	Vinegar
08.02	Fried or roasted foods: <ul style="list-style-type: none"> <li>A. Fried potatoes, fritters and the like</li> </ul>



	B. Of animal origin
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: A. Powdered or dried: I. With fatty character B. any other form than powdered or dried: I. With fatty character
08.04	Sauces: B. With fatty character e.g. mayonnaise, sauces derived from mayonnaise, salad creams and other oil/water mixtures e.g. coconut based sauces
08.05	Mustard (except powdered mustard under heading 08.14)
08.06	Sandwiches, toasted bread pizza and the like containing any kind of foodstuff A. With fatty substances on the surface
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 500

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Issue Date: 1st October 2009