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UK



Confidential report for:

Kalex Films Ltd

FAO: Charles Read
Crabtree Road
Forest Vale Industrial Estate
Cinderford
Gloucestershire
GL14 2YN
UK

Report on:

Overall & Specific migration from food contact materials

Report number: AC/REP/160536/33 ♦ Issue date: 18th March 2024

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SAMPLE INFORMATION

Company	: Kalex Films Ltd
Product description	: Clear 100%rPET
Campden reference	: AC/160536/33
Date received	: 8 th February 2024
Condition	: Free from any apparent or obvious physical defects
Storage	: Ambient
Date of analysis	: 8 th February – 15 th March 2024
Test data	: DP/A3 p75 & TG/A2 p51

METHODS AND REFERENCES

Testing programs for overall migration are devised in accordance with the BS EN ISO 1186 series of standards and Commission Regulation No. 10/2011 as amended.

Methods used for this work and accredited by UKAS are listed in the Schedule of Accreditation, a copy of which is available from: <http://www.campden.co.uk/campdenbri/qualityofservice.php>

Method TES-AC-500 is based on BS EN 1186:2022 part 2 - Test methods for overall migration in vegetable oils.

Method TES-AC-501 is based on BS EN 1186:2022 part 3 - Test methods for overall migration in evaporable simulants.

Four test specimens are used in each overall migration test performed with food stimulants to ensure that a minimum of three valid test results are obtained.

Sunflower oil is used as an alternative to rectified olive oil - "reference stimulant D". The sunflower oil used has characteristics in accordance with those specified in Annex A of BS EN 1186-1:2002.

CALCULATION OF RESULTS

Where a test result for a replicate is found to be less than the limit of detection the calculated numerical value, *M* (as defined in clause 3.6.1 of BS EN 1186-3:2002 for aqueous testing and clause 8.1 in BS EN 1186-2:2002 for olive oil testing) and not the limit of detection is used for that replicate for the purpose of calculating the mean overall migration result. Where the calculated numerical value is negative, a value of zero is used for purposes of calculating the mean.

Concerning overall migration into oil, unless this report includes an explicit statement to the contrary, reduction factors are not taken into account when reporting the results.

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.

OVERALL MIGRATION: TEST CONDITIONS & RESULTS

Method : TES-AC-500 & 501 (UKAS accredited)

Contact time/temp : 10 days @ 40°C

Overall migration limit : 10 mg/dm²

Simulant	Test Results mg/dm ²				Mean test Result mg/dm ²	Technique	Contact Area
10% (v/v) Ethanol in Aqueous Solution	<0.10	<0.10	<0.10	0.30	0.1	Total Immersion	1 dm ²
3% (w/v) Acetic Acid in Aqueous Solution	0.10	0.10	0.20	0.70	0.3	Total Immersion	1 dm ²
Vegetable Oil	<0.05	<0.05	<0.05	<0.05	<0.1	Total Immersion	1 dm ²

SPECIFIC MIGRATION: TEST CONDITIONS & RESULTS

Method : TES-AC-812 (Non-UKAS)

Simulant : 10% (v/v) Ethanol in Aqueous Solution

Contact time/temp : 10 days @ 40°C

Contact area : 1 dm²

Compound	Result (mg/kg)			Mean Migration (mg/kg)	SML (mg/kg)
Terephthalic Acid	<0.10	<0.10	<0.10	<0.1	7.5
Isophthalic Acid	<0.10	<0.10	<0.10	<0.1	5.0
Ethylene glycol *	<1.8	<1.8	<1.8	<1.8	30
Diethylene glycol *	<1.8	<1.8	<1.8	<1.8	30

Method : TES-AC-812 (Non-UKAS)

Simulant : 3% (w/v) Acetic Acid in Aqueous Solution

Contact time/temp : 10 days @ 40°C

Contact area : 1 dm²

Compound	Result (mg/kg)			Mean Migration (mg/kg)	SML (mg/kg)
Terephthalic Acid	<0.10	<0.10	<0.10	<0.1	7.5
Isophthalic Acid	<0.10	<0.10	<0.10	<0.1	5.0
Ethylene glycol *	<4.2	<4.2	<4.2	<4.2	30
Diethylene glycol *	<4.2	<4.2	<4.2	<4.2	30
Titanium dioxide ¹	<0.04	<0.04	<0.04	<0.04	60

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Aluminium	<0.04	<0.04	<0.04	<0.04	1
Antimony	<0.01	<0.01	<0.01	<0.01	0.04
Arsenic	<0.01	<0.01	<0.01	<0.01	ND
Barium	<0.01	<0.01	<0.01	<0.01	1
Cadmium	<0.002	<0.002	<0.002	<0.002	ND (<0.002)
Calcium	<9	<9	<9	<9	60
Chromium	<0.01	<0.01	<0.01	<0.01	ND
Cobalt	<0.01	<0.01	<0.01	<0.01	0.05
Copper	0.04	0.04	0.04	0.04	5
Iron	<0.04	<0.04	<0.04	<0.04	48
Lead	<0.01	<0.01	<0.01	<0.01	ND
Lithium	<0.01	<0.01	<0.01	<0.01	0.6
Magnesium	<0.2	<0.2	<0.2	<0.2	60
Manganese	0.02	0.02	0.02	0.02	0.6
Mercury	<0.01	<0.01	<0.01	<0.01	ND
Nickel	<0.01	<0.01	<0.01	<0.01	0.02
Potassium	<0.2	<0.2	<0.2	<0.2	60
Sodium	0.4	<0.2	0.4	0.3	60
Zinc	<0.09	<0.09	<0.09	<0.09	5

Method : TES-AC-812 (Non-UKAS)
 Simulant : Vegetable Oil
 Contact time/temp : 10 days @ 40°C
 Contact area : 1 dm²

Compound	Result (mg/kg)			Mean Migration (mg/kg)	SML (mg/kg)
Terephthalic Acid	<0.10	<0.10	0.10	<0.10	7.5
Isophthalic Acid	<0.10	<0.10	<0.10	<0.10	5.0
Ethylene glycol *	<0.3	<0.3	<0.3	<0.3	30
Diethylene glycol *	<0.3	<0.3	<0.3	<0.3	30

* In accordance with Annex V of EU Commission regulation 10/2011 (2.2 screening approaches) the migration of non-volatile compounds Ethylene Glycol and Diethylene Glycol were determined by the overall migration result under conditions at least as severe as those used for specific migration.

¹Quantified as titanium.