Product Specification

Product Title: TRAY LIDDING FILM PE 50MU 135MM 500 MTR/ROLL

Product Code: WPD054135

Product Size: ALL SIZES 50PF 12/40mu PLAIN AF LAMINATE

Declaration of Compliance for Food Contact Articles

European Union

The composition of the above-mentioned film is compliant with Commission Regulation (EU) No 10/2011 and as appended by EU/1416/2016, under the condition that the finished article meets the following migration limits

OML 10 mg/dm² or 60 mg/kg food (Article 12).

PM Ref	FCM	CAS Nos.	SUBSTANCES	LIMITATIONS
16990	227	107-21-1	Ethylene glycol	SML(T) = 30 mg/kg
24910	785	100-21-0	Terephthalic Acid	SML = 7.5 mg/kg
35760	398	1309-64-4	Antimony Trioxide	SML = 0.04 mg/kg (expressed as antimony)

All monomers and additives used in the composition of the above product are listed in the Union list of authorised substances, see Annex I of Commission Regulation (EU) No 10/2011 and as appended by EU/1416/2016.

This film grade may also contain additives which are also food additives and flavouring ('Dual Use Additives'), based on the provisions of Article 11 (3) of **Regulation (EU) No 10/2011**, and as appended by EU/1416/2016, as proprietary substances. These are present at less than 1% of minimum limits allowed in food identified in Regulation (EU) No 1333/2008 as amended and calculated total w/w percentage content less than 1% of any SML. These may be disclosed to an independent third-party testing laboratory for performance of necessary tests, subject to secrecy obligations.

Substances listed in Annex II of the Regulation are either not intentionally added or, when used, worst case calculations and or measurement ensures compliance with the restrictions of Annex II.

The above-mentioned film is produced according to our quality management systems, which comply with the requirements of the Regulation (EC) No 2023/2006, on good manufacturing practice for materials and articles intended to come into contact with food.

Traces of substances authorised as food additives can be present. If present migration into foodstuffs is not reasonably expected to exceed the limits, specified in the relevant food legislation.

The above-mentioned film is compliant with the relevant requirements of the Framework Regulation (EC) No 1935/2004, presuming further appropriate processing of the film following the Good manufacturing practice Regulation (EC) No 2023/2006.

In Europe, in the case of incomplete compliance in one country, the product can, on the basis of its full compliance in at least one Member State of the European Union, be legally placed on the market for direct food contact in all Member States according to the Article 34-36 of **The Treaty on the Functioning of the European Union** (TFEU). Moreover, it is our understanding that the Swiss Ordinance SR 817.023.21, for its part on plastic food contact materials and articles, is in line with the EU legislation. Therefore, compliance with the Swiss Ordinance SR 817.023.21 is implied.

Migration Data

The basic rules necessary for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs are harmonized at European level. Commission Regulation (EU) No 10/2011, and as appended by EU/1416/2016, describes the methods to determine migration by using food simulants. The limits of specific migration for allowed monomers and additives are listed in Annex I of Commission Regulation (EU) No 10/2011, and as appended by EU/1416/2016. The same Regulation sets the limit for overall migration of the finished article at 10mg/dm².

Migration testing has been performed on representative samples based on the conditions covered by Annex V of Commission Regulation (EU) No 10/2011, and as appended by EU/1416/2016, as below. It is the responsibility of both the producer of the finished food-contact articles as well as the industrial food packagers to ensure that these test conditions cover the actual conditions of use. Please refer to Commission Regulation (EU) No 10/2011 and as appended by EU/1416/2016.

The migration tests for materials and articles intended to come into contact with foodstuffs should be carried out in accordance with Commission Regulation (EU) No 10/2011, Article 18.

OVERALL MIGRATION: TEST CONDITIONS & RESULTS

Limit 10 mg/dm² or 60 mg/Kg Food (Article 12).
Method: TES-AC-500 & TES-AC-501 (UKAS accredited)
Contact time/temp: 10 days @ 40°C

SIMULANT	TECHNIQUE	CONTACT AREA	COMPLIANT
3%(w/v) Acetic acid in an aqueous solution	Pouch Technique	2.0dm2	Yes
10%(v/v) Ethanol in an aqueous solution	Pouch Technique	2.0dm2	Yes
Sunflower Oil	Pouch Technique	2.0dm2	Yes

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 and as appended by EU/1416/2016.

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 1186:2002 parts 2, 4, 6, 8.
Global (overall) migration from packaging materials into olive oil food simulants by total immersion, single side contact by cell technique, single side contact by pouch technique and by article filling technique.

Method TES-AC-501 is based on BS EN 1186:2002 parts 3, 5, 7, 9 and 14.
Global (overall) migration from packaging materials into aqueous food simulants and substitute fatty food simulants by total immersion, single side contact by cell technique, single side contact by pouch technique and by article filling technique.

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.

Based on worst case calculations, we can confirm that all proprietary substances are calculated to be present at concentrations below 1% of the respective specific migration limit and are therefore considered to be compliant in all Food Simulants listed in Regulation (EU) No 10/2011, and as appended by EU/1416/2016.

Based on the above our conclusion is that this film can be used for all food types any long term storage at room temperature or below, including heating up to 70°C for up to 2 hours, or heating up to 100 °C for up to 15 minutes or heating to temperatures above 175 °C for up to 2 hours

If a customer considers his application deviating from the conditions covered by the test conditions highlighted in the table here above, they are responsible for performing the appropriate testing.

Important Information: This evaluation has been performed on a typical product sample produced under standard production conditions as per our manufacturing standards. Specific conversion conditions at our customers may change the profile of potential migrants and lead to different results on the final packaging material. Such changes are beyond our knowledge. Therefore, please be informed that it is the responsibility of both the producer of the finished food-contact articles as well as the industrial food packagers to make certain that such articles, under actual conditions of use, meet the above referenced requirements.

General requirements applicable in all countries

Manufacturers using the above product for further processing, must ascertain, through the appropriate tests, that these articles comply with the above-mentioned restrictions/limitations (OML, SML etc.); furthermore, these articles must comply in all countries with the general regulatory requirement that they do not bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.
The present review only refers to applicable food-contact regulations. Medical and pharmaceutical applications are not considered by these regulations.

Product Specification

Customer Approval of Specification	
Please sign and return this specification to **technical@scobie-junor.co.uk** to confirm formal acceptance of this specification. All specifications issued will be deemed to be accepted if no communication to the contrary is received after 10 working days.	
Signature:	
Print name:	
Position:	
Date:	

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