



Piacenza, December 7<sup>th</sup>, 2016

**Messrs**  
**UNILEVER SUPPLY CHAIN COMPANY AG**  
**Spitalstrasse 5**  
**CH-8201 SCHAFFHAUSEN**

**DECLARATION OF COMPLIANCE FOR FLEXIBLE PACKAGING MATERIALS AND  
ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD  
EUROPEAN LEGISLATION**

**RE:**

TYPE	STRUCTURE	FOOD CONTACT LAYER	SAFTA REF. <sup>CE</sup> CODE
OXYBLOC/M 12 50	PET/Met 12µm - PE 50µm	PE 50µm	Y3B062002

The information that follows covers the regulatory position of our subject products as supplied by us to your company, in unprinted form. The surface-to-volume ratio considered hereinafter is 6dm<sup>2</sup> (lamine) per 1kg (food).

We declare hereby that our subject products comply with the following legislations concerning packaging in contact with foodstuffs, each as relevant:

❖ **EUROPEAN COMMUNITY**

- Commission Regulation (EC) No 1935/04/EC on materials and articles intended to come into contact with food;
- Commission Regulation (EC) No 2023/06/EC on good manufacturing practice for materials and articles intended to come into contact with food;
- Commission Regulation (EC) No 10/2011 on plastic materials and articles intended to come into contact with food (as amended to date) insofar as their plastic components and their adhesives, inks and lacquers, if and as applicable, are concerned;

❖ **ITALY**

- Decreto Ministeriale 21/03/1973 (as amended to date) insofar as migration testing requirements;
- DPR 777/82 (as amended to date).

❖ **FURTHER REGULATORY REFERENCES**

Please note that our subject products

- comply with Commission Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives (BADGE, BFDGE and NOGE) in materials and articles intended to come into contact with food;



- are produced without the use of recycled plastic materials, therefore bear no obligations with respect to Commission Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with food.

❖ INFORMATION ON COMPONENTS NOT COVERED BY SPECIFIC REGULATIONS FOR 'FOOD CONTACT' APPLICATIONS

▪ ALUMINIUM FOIL

No specific regulatory coverage exists for the use of aluminium foil as an inner layer of materials and articles intended for food contact applications. In this vacuum, you might be interested in noting that, as per the statements provided by our relevant suppliers, the Alu.film incorporated in our subject product is compositionally compliant with EN 602 (*Aluminium and aluminium alloys - Wrought products - Chemical composition of semi-finished products used for the fabrication of articles for use in contact with foodstuff*).

▪ INKS AND LACQUERS (IF AND AS RELEVANT)

As per the statements provided by our relevant suppliers, the inks and lacquers that we use to print our complete range of products (both in case of outside printing and 'sandwich' printing, as relevant) are designed and produced in compliance with the current editions of "EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles" and "EuPIA Exclusion Policy".

For outside printed materials, we remind you that only their unprinted side can come into direct contact with the packed food.

As for the "Detailed rules on good manufacturing practice" regarding the processes involving the application of printing inks to the non-food contact side of a material or article quoted in the Annex to Commission Regulation (EC) No 2023/06/EC, we remark that our entire production processes, including the formulation and the application of the printing inks, are thoroughly monitored through our Quality Control and Quality Assurance systems, backed up by apposite documentation.

MIGRATION TESTS

No harmonized legislation exists at European level addressing expressly Multimaterial Multilayer Materials (MMMs) intended to come into contact with food (such are our subject products). The most comprehensive regulatory text in this respect remains, to date, Commission Regulation (EC) No 10/2011 on plastic materials and articles intended to come into contact with food (as amended<sup>(1)</sup>). This Regulation does not require Migration tests to be performed for MMMs. We care to address this issue nonetheless and provide you here below with a set of information that you will use to your best convenience.

OVERALL MIGRATION LIMIT

The documentary and/or analytical feedback in our hands confirms that the subject products meet the Overall Migration Limit (10mg/dm<sup>2</sup> or 60mg/kg) set by Commission Regulation (EU) No 10/2011<sup>(1)</sup> in the following test conditions:

- up to 10 days at 40 °C with simulants A, B and D2.

Please note the guidelines provided by the European Commission in this respect:



- Standardized Testing Condition OM2 (10 days at 40 °C) covers “Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature  $T$  where  $70\text{ °C} \leq T \leq 100\text{ °C}$  for a maximum of  $t = 120/2^{(T-70)/10}$  minutes.” (table 3 of the annex of Commission Regulation (EU) No 1416/2016);
- “To demonstrate compliance with the overall migration limit for all type of foods testing in distilled water or water of equivalent quality or food simulant A and food simulant B and simulant D2 shall be performed.” (chapter 4 of annex III of Commission Regulation (EU) No 10/2011 ).

### SPECIFIC MIGRATION LIMITS

In light of the provisions of Commission Regulation (EU) No 10/2011 (e.g. consideranda 32, whereby “As migration testing is complex, costly and time consuming it should be admissible that compliance can be demonstrated also by calculations, including modelling, other analysis ...”) and based on the information provided by our raw material suppliers and/or on any relevant analytical evidence (‘worst case scenarios’), we declare that all the Specific Migration Limits applicable to our subject products are fully respected.

As for the migration of PAA’s (Primary Aromatic Amines), we have commissioned to accredited laboratories a significant number of analytical tests to cover our wide range of products. The relevant reports in our hands demonstrate the full compliance of our subject products to the applicable regulatory requirements (SML: 10ppb) in the following test conditions:

- up to 10 days at 60 °C with simulant ‘B’.

In this respect, please note that :

- simulant ‘B’ was selected in compliance with the method of analysis LMGB S 35L 00.00-6:1995/COR:2002;
- “Testing for 10 days at 60 °C shall cover storage above 6 months at room temperature and below, including hot-fill conditions and/or heating up to  $70\text{ °C} \leq T \leq 100\text{ °C}$  for maximum  $t = 120/2^{(T-70)/10}$  minutes.” [Commission Regulation (EU) No 2016/1416, annex, (5) (d)].

### ‘DUAL USE’ SUBSTANCES

Substances authorized both for the production of plastic materials and as additives and flavourings for the food manufacturing industry (as referred to by European Regulations no. 1333/08 and no. 1334/08) might be incorporated within the raw materials composing the subject products. Should the composition of the foodstuff being packed involve specific restrictions that might require any particular insight in this respect, do not hesitate to revert with details for us to focus our investigation accordingly.

### LIABILITY

This declaration is issued in observance of the requirements of Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. It is intended for our subject customer only and no liability to any third party is accepted from our end. It is the only declaration of compliance that we are bound to issue with regards to our subject products, unless otherwise agreed to by our companies through separate arrangements. Should you need to receive any further regulatory feedback, please make sure you send us your relevant enquiry, accompanied by the applicable regulatory text(s) (in English) which our subject products are being required to

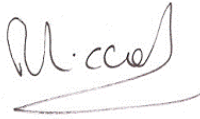
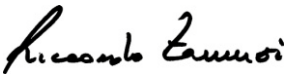


comply to.

VALIDITY

This declaration replaces all previous equivalent declarations referred to our subject products, is valid as of today and remains valid until substantial changes are introduced in the composition and/or production process of our subject products or until amendments and/or upgradings take place in the applicable laws that may affect their regulatory status as detailed here above.

We remain available and send you our best regards.

	
Paola Riccardi - R&D Dept.	Riccardo Zammori - R&D Manager

- (1) Article 12 (“Overall Migration Limit”) of Commission Regulation (EU) No 10/2011 states the following:
1. Plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per  $dm^2$  of food contact surface ( $mg/dm^2$ ).
  2. By derogation from paragraph 1, plastic materials and articles intended to be brought into contact with food intended for infants and young children, as defined by Commission Directives 2006/141/EC and 2006/125/EC, shall not transfer their constituents to food simulants in quantities exceeding 60 milligrams of total of constituents released per kg of food simulant.

Disclaimer

We declare that our subject products, in the form in which they are delivered and in their original packaging, comply with the aforementioned applicable laws in force at the time of their production. In no event we shall be liable for the compliance of the product with the applicable laws should the products themselves be modified, altered or changed in any manner whatsoever by the purchaser, also in relation or as a consequence of their commercial uses.

The food packer is responsible for ensuring that the finished food packaging complies with the applicable migration limits in the food itself under actual conditions of use. Furthermore, the food packer is responsible for verifying the possible interactions of the subject products with the foodstuffs, which are to be checked prior to use and in function of the end uses.

This declaration covers exclusively the regulatory compliance of our subject products. It may therefore not be regarded as a statement concerning their technical suitability for the intended use. For all technical aspects related to our subject products (including their warranty terms) please refer to their relevant technical documentation (i.e. Product Information Sheet).