

## Declaration of Compliance for Materials intended to come into contact with Food

This is to declare that PVC plastic film **WEEGAL FILM: KOEX 810, KOEX 812, KOEX 814 and CORAL FILM MANUALE 8** is suitable for the packaging of **MEAT, FRUIT, VEGETABLES, CHEESE, FISH AND FOOD** for which either no test to measure the migration of substances is envisaged or tests are envisaged with simulants A, B and D2 with a reduction factor of X/3 or above as set out by Annex III of Regulation (EU) no. 10/2011. In addition, the above-mentioned material:

### 1) COMPLIES with the following European (EU) laws:

- Directive 78/142/EEC of 30/01/1978
- Regulation 1935/2004/EC
- Regulation 1895/2005/EC
- Regulation 2023/2006/EC as amended
- Regulation (EU) no. 10/2011 of 14 January 2011 as amended
- Resolution AP (92) 2 of the Council of Europe of 19 October 1992

### 2) CONTAINS the following components subject to specific migration limits:

- "Zinc" (Annex II to Regulation (EU) No 10/2011) with SML = 5 mg/kg
- "polyesters of 1,2-propanediol and/ or 1,3- and/or 1,4-butanediol and/ or polypropyleneglycol with adipic acid, which may be end-capped with acetic acid or fatty acids C 12-C 18 or n-octanol and/or n-decanol" (FCM subst. no. 73 and/or 797) with SML(T) = 30 mg/kg
- "octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate" (FCM substance no. 433) with SML = 6 mg/kg
- "tri-n-butyl acetyl citrate" (FCM substance no. 138) with SML(T) = 60 mg/kg
- "soybean oil, epoxidised" (FCM substance no. 532) with SML = 60 mg/kg
- "adipic acid, bis(2-ethylhexyl) ester" (FCM substance no. 207) with SML = 18 mg/kg

### 3) MAY CONTAIN TRACES of substances not directly used in our formulations such as:

- "vinyl chloride" (FCM substance no. 127) with QM = 1 mg/kg in final product and SML = ND (<0,01 mg/kg)
- "acetic acid, vinyl ester" (FCM substance no. 231) with SML = 12 mg/kg
- "1,4-dihydroxybenzene" (FCM substance no. 295) with SML = 0,6 mg/kg
- "formaldehyde-1-naphthol, copolymer" (FCM substance no. 640) with SML = 0,05 mg/kg
- "2,6-di-tert-butyl-p-cresol" (FCM substance no. 315) BHT (dual use E321) with SML = 3 mg/kg
- "tert-butyl-4-hydroxyanisole" (FCM substance no. 635) BHA (dual use E320) with SML = 30 mg/kg
- "N,N-Diethylhydroxylamine" (CAS no. 3710-84-7) with SML = 0,05 mg/kg
- "peroxides" with SML = 0,05 mg/kg of active oxygen in distilled water for 24 h at 23 °C
- "isododecane" (CAS no. 31807-55-3) with SML = 6 mg/kg.

Such substances, which are not intentionally added, can derive from the presence of impurities in the raw materials or form as reaction and degradation products.

### 4) the following ARE NOT USED to produce the material:

- Phthalates (esters of phthalic acid)
- Substances defined as "SVHC" included or proposed to be included ("candidate list") in Annex XIV of regulation (EC) no. 1907/2006 (REACH), substances in nano-form
- Bisphenol A (2,2-bis(4-hydroxyphenyl)propane)
- Substances defined as "BADGE, BFDGE, NOGE" subject to Regulation 1895/2005/EC.

### 5) PRESENCE OF DUAL USE ADDITIVES SUBJECT TO REGULATIONS 1333/08/EC and/or 1334/08/EC:

- E470a
- E471
- E493
- E570
- N.FL 09.511

According to experimental data and/or theoretical calculations, said substances comply with Regulation (EU) no. 10/2011, art 11 paragraph 3. Users of food contact materials are responsible for warning our company of any restrictions caused by the composition of the food to be packaged (additives and/or flavourings).

### 6) OVERALL AND SPECIFIC MIGRATION TESTING CONDITIONS:

Overall and specific migration testing conditions (Regulation (EU) no. 10/2011) are:

- Simulants A, B and D2: 10 days at 40 °C (OM2) also including OM1 and OM3 contact conditions as specified in annex V of Regulation (EU) no. 10/2011. A reduction factor of X/3 or above is then applied to the D2 test result in accordance with Regulation (EU) no. 10/2011
- Surface area: 1 dm<sup>2</sup>; Volume: 100 ml.

Overall and specific migration limits are not exceeded in the conditions of use envisaged for the materials and in compliance with the "Safety precautions". Suitable supporting information is available for monitoring bodies, obtained from experimental data and/or theoretical calculations on the overall and specific migration levels of the components subject to restrictions. Lab tests and theoretical calculations (in "worst case" conditions) have been carried out assuming that the maximum ratio between the surface area in contact with the food and the volume used to determine the compliance of the material is of 6 dm<sup>2</sup> for 1 kg of packaged food.

We would like to point out that other substances listed in Annex I of regulation (EU) no. 10/2011 - for which there are no restrictions and which are therefore not mentioned in this Declaration of Compliance - may also be used.

Pursuant to Regulation (EC) No. 1935/2004, the material is manufactured in compliance with good manufacturing practices so that, under the defined conditions of use, it does not release its constituents to food in quantities which could endanger human health, bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics thereof (art 3). The compliance of the material can be demonstrated in a technical dossier supporting this declaration, which will be made available to the competent authorities requesting it. Used components are subject to community authorization as per (EC) Regulation N. 1935/2004 Art. 11. When material is placed on the market, its labelling complies with what settled in art.15 of said Regulation. Material traceability is ensured throughout entire product lifecycle, so that checks, defective products recall, information to consumer and liability charges can be facilitated, according to what's established by Art 17 of (EC) Regulation N. 1935/2004.

#### SAFETY PRECAUTIONS:

The material is suitable for:

- any food contact at frozen and refrigerated conditions
- any long term storage (up to 30 days) at room temperature or below (excluding the above-mentioned conditions of freezing and refrigerating) and included when packed under hot-fill conditions and / or heating up to a temperature T, where  $70\text{ }^{\circ}\text{C} \leq T \leq 100\text{ }^{\circ}\text{C}$  for a maximum of  $t = 120/2^{(T-70)} / 10$  minutes
- any food contact conditions that includes hot-fill and / or heating up to a temperature T, where  $70\text{ }^{\circ}\text{C} \leq T \leq 100\text{ }^{\circ}\text{C}$  for maximum of  $t = 120/2^{(T-70)} / 10$  minutes, which are not followed by long term room temperature or refrigerated storage

The material is not suitable for:

- alcoholic foods or food entirely made of fats or preserved in oily or alcoholic mediums
- contact times and temperatures different from those indicated above
- use in conventional and microwave ovens

#### PRODUCER:

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#### VALIDITY OF THIS DECLARATION

- This declaration shall be valid from the date below and will be replaced in case of substantial changes in the composition or manufacturing of the material, which modify the essential requirements for its compliance, or in case of changes in the applicable regulation
- The information herein provided refers to the products indicated and may not apply if the product is used in combination with other products or in conditions different from the ones listed above.

Vignola, 05/11/2020

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