

# DECLARATION of COMPLIANCE

For items intended to come into contact with foodstuffs (\*)

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## 1) IDENTITY AND ADDRESS OF BUSINESS OPERATOR

Company: **Fucine Film Solutions S.r.l.**  
Address: Via Careno 8, 21040 Vedano Olona (VA) – Italia

## 2) IDENTITY AND ADDRESS OF MANUFACTURER OF THE PRODUCT

Company: **Fucine Film Solutions S.r.l.**  
Production facility: Fucine di Ossana - manufacturing site  
Address: Via dell'Artigianato, 6 - 38026 – Fucine di Ossana - Trento – Italia

## 3) IDENTITY OF THE MATERIALS

Trade name: **303\_00, 306\_00, 324\_3A, 327\_00, 335\_3A, 355\_00, 383\_00, 0033, 0061, K054, 0373, 1736, 9680**  
Color  
Surface: **BOB0, B050**  
Type of product: **Plastic film – rigid PVC**  
Treatment: **none**  
Food contact side \* **both sides**

\*means the surface of material that is directly in contact with the food.

## 4) DATE AND VALIDITY

Issue B Rev. 8 Date of declaration: 18/03/2015  
Validity: This Declaration replaces any previous versions and it is intended only for your Company. Due to the progress and evolution of national and international regulations and laws, we recommend that you periodically check the validity of the content of this document by contacting our offices for an update.

## 5) CONFIRMATION OF COMPLIANCE TO REGULATION (EC) No 1935/2004

This material is in compliance with the relevant requirements set out in Article 3 of Regulation (EC) No 1935/2004 under intended and foreseeable use.  
Traceability as defined in article 17 of this Regulation is compliant with the Industrial Guidelines on traceability of materials and articles for food contact –part 4: traceability applied in the plastic chain.

## 6) ADEQUATE INFORMATION RELATIVE TO SUBSTANCES WITH RESTRICTIONS AND SPECIFICATIONS SET OUT IN Annex I AND II 10/2011

This material is manufactured according to good manufacturing practice as set out in Commission Regulation (EC) No 2023/2006.  
This material complies with the compositional requirements set out in Chapter II – section 1 of Regulation 10/2011 (Authorized substances) and following amendments .  
Substances used in manufacturing of this product, which are not yet regulated by EU Directive, comply with National Laws or Recommendation of the Council of Europe or article 3 of the Regulation (EC) No 1935/2004.

### Colorants and pigments

#### Resolution AP(89)1

Pigments and colorants used are in compliance with purity criteria defined in Resolution AP (89) 1. No rules have been set out yet at EU level for the risk assessment and use of colorants in plastics. Therefore their use should remain subject to national law. That situation should be reassessed at a later stage.

#### Italian Decree DM 21/03/1973

According to Italian Law (Decreto Ministeriale 21/03/1973 – section 7 annex IV and amendments), for colored materials the optical transmission rate % after global migration tests into simulants has to be carried out to guarantee a minimum 95% transmission rate.

Compliance is described in the below paragraph.

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## 7) ADEQUATE INFORMATION RELATIVE TO SUBSTANCES WITH RESTRICTIONS IN FOOD

This material contains some substances which are subject to a restriction in food or listed with a SML (specific migration limit). These substances are present in the main ingredients of the film:

Substance name	REF N°	Restriction SML (mg/kg) Specific migration limit
acetic acid, vinyl ester	10120	12
acrylic acid, n-butyl ester	10780	6
Butadiene	13630	1 mg/kg in final product ND
1,4-dihydroxybenzene	15940	0,6
Divinylbenzene	16690	ND
methacrylic acid, methyl ester	21130	6
vinyl chloride	26050	1 mg/kg in final product ND
adipic acid, bis(2-ethylhexyl) ester	31920	18
tert-butyl-4-hydroxyanisole	40720	30
2,6-di-tert-butyl-p-cresol	46640	3
2,4-dimethyl-6-(1-methylpentadecyl) phenol	49485	1
di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	50320	0,006 (expressed as tin)
formaldehyde-1-naphthol, copolymer	54930	0.05
mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	67680	1,2 (expressed as tin)
octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propion	68320	6
soybean oil, epoxidised	88640	60
thiodipropionic acid, didodecyl ester	93120	5
glycerides, castor-oil mono-, hydrogenated, acetates	55910	60
dodecylbenzenesulphonic acid	52000	30
2-methyl-4-isothiazolin-3-one	66755	0.5
triisopropanolamine	94560	5
ethylene oxide	17020	ND

Potential SML of those listed and any other substances has been tested or calculated by screening approach, overestimation of migration content of the substance in the material applying the worst case calculation.

For information concerning substances contained in the other minor ingredients and/or dual use additives we are dependant upon the willingness our suppliers to provide the necessary information to us.

Upon request and when available we will provide more details in confidence.

## 8) SPECIFICATIONS ON THE USE OF THIS FILM

This product is a material not yet in contact with food.

**We have no control over any materials that might be added to achieve conversion into final**

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**article or any additional processing involved. We do not have knowledge about the conditions under which the final article may be used or physical or other changes that could take place during the final use of it.**

## (i) type or types of food with which it is intended to be put in contact (\*)

The product is suitable to be used with ALL TYPE OF FOODS, in 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.

The overall and specific migration limits of metals and primary aromatic amines (annex II of Reg. (EU) No 10/2011) are respected in accordance with the usage conditions above mentioned.

The computations have been arranged assuming that 1 kg of food comes in contact with 6 dm<sup>2</sup> of packaging material.

Test Conditions and simulants:

Food Simulant	Time and Temperature
Acetic Acid 3% w/V (B)	10 days at 40°C
Ethanol 10% V/V (A)	10 days at 40°C
Rectified olive oil ( D2)	10 days at 40°C

Simulants and test conditions were chosen in compliance with Regulation (UE) n. 10/2011).

The material contains substances regulated by Regulations (EC) n. 1333/2008 and 1334/2008 as amended ("dual use" substances):-

Substance name	REF N°	Restriction SML (mg/kg) Specific migration limit
stearic acid salts	89040-24550 (E572) (E570)	--
talc	92080 (E553b)	--
2,6-di-tert-butyl-p-cresol	46640 (E321)	3
Sodium, potassium and calcium salts of fatty acids	(E470A)	--
Potassium phosphates.	(E340)	--
Sodium carbonates.	(E500i)	--
Sodium sulphates.	(E514)	--
Sodium hydroxide.	86720 (E524)	--
silicon dioxide	86240 (E551)	--
tert-butyl-4-hydroxyanisole	40720 (E320)	30
Titanium dioxide	E (171)	--
Hydrogen Chloride	59990 (E507)	--

## (ii) ratio of food contact surface area to volume used to establish the compliance of the material :

Tests have been carried out on film samples 1 dm<sup>2</sup> size.

To confirm the compliance to the DM 21/3/73 requirements, a % **transmittance after migration** into

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simulants have been carried out.

All results obtained confirm the compliance to specifications set out in the DM 21/03/1973.

Those data are based on evaluation of migration test results carried out on representative samples at above listed conditions and food simulants.

**In case of usage of this film at temperature or for times differing from this test condition (e.g. thermoforming, hot-filling, storage) or when using the films in contact with foodstuffs or mix of simulants different from the above simulants used, further migration tests may be needed as indicated in the relevant Regulations.**

It is responsibility of the manufacturer or user of the **final article** to ensure that migration requirements are met and to verify the organoleptic properties for the technological suitability of the final article.

**Supporting documents** - Article 16 Regulation 10/2011.

Appropriate documentation to demonstrate that the materials from intermediate stages of their manufacturing as well as the substances intended for the manufacturing of those materials comply with the requirements of this Regulation will be made available by our Company to the national competent authorities on request.

That documentation contains the conditions and results of testing, calculations, including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance.

### 9) FUNCTIONAL BARRIER

No functional barrier is used to manufacture this film.

### 10) GENERAL RECOMMENDATIONS

By complying with the above regulations, our duty to exercise due care with regard to the suitability of the products supplied by us for use in contact with foodstuffs has been fulfilled.

This confirmation of compliance with food contact legislation relates only to the above mentioned product and not to the finished article produced with or without addition of additives, coatings or other substances since we have no control over any materials that might be added to achieve conversion into final article or any additional processing involved or the conditions under which the final article may be used.

This document reflects the present legal environment, based on our best knowledge as of the issue date of this letter.

Should you need any further information, please do not hesitate to contact us.

Fucine Film Solutions S.r.l.

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Annex 1

### **Specific migration limits** – article 11 Regulation 10/2011

Plastic materials and articles shall not transfer their constituents to foods in quantities exceeding the specific migration limits (SML) set out in Annex I. Those specific migration limits (SML) are expressed in mg of substance per kg of food (mg/kg). For substances for which no specific migration limit or other restrictions are provided in Annex I, a generic specific migration limit of 60 mg/kg shall apply.

### **Overall migration limit** - Article 12 Regulation 10/2011.

Plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm<sup>2</sup> of food contact surface (mg/dm<sup>2</sup>).

To ensure that migration requirements are met, the final migration test must be carried out on the final article in contact with the foodstuffs or using adequate food simulants for a certain time and at the temperature defined in the relevant Directives (article 18).

The sample shall be placed in contact with the food simulant representing the worst of the foreseeable conditions of use as regard contact time and as regard contact temperature; the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

On the base of the actual knowledge, we carried out migration tests according to Annex V - Chapter 2 - Testing for specific migration of materials and articles not yet in contact with food, to ensure that this material respects the overall and specific migration requirements, using food simulants for a certain time and at the temperature defined in the Directive 97/48/CE (amendment 82/711/CEE) dated July 29<sup>th</sup> 1997 and 85/572/CEE (conditions and food simulants)

### **Transitional provisions of Supporting documents - Regulation UE 10/2011**

According to article 22 of Regulation 10/2011, the following transitional provisions are valid:

- As from 1 January 2013 the supporting documents referred to in Article 16 for materials, articles and substances placed on the market until 31 December 2015, may be based on:

(a) the rules for migration testing set out in Article 18 of this Regulation; or

(b) the basic rules for overall and specific migration testing set out in the Annex to Directive 82/711/EEC.

- As from 1 January 2016, the supporting documents referred to in Article 16 shall be based on the rules for migration testing set out in Article 18.

Declaration of compliance need, in principle, only to be updated when substantial changes in the production bring about changes in the migration or when new scientific data are available.

In order to limit the burden to business operators, materials which have been lawfully placed on the market based on the requirements set out in Directive 2002/72/EC should be able to be placed on the market with a declaration of compliance based on supporting documentation in accordance with Directive 2002/72/EC until 5 years after the adoption of the Regulation.