

DECLARATION OF COMPLIANCE for: punnets, lids and kit line in PET

The company **INFIA srl**, viale Caduti di via Fani, 85 Bertinoro (FC - ITALY), declares that the family range here above are manufactured under certified management systems ISO 9001 and BRC-IoP.

We confirm that this product fulfils the requirements on materials used for articles intended to come into contact with food as described in the following European and national legislation

- Framework Regulation 1935/2004 EC
- Regulation 1895/2005 EC
- Regulation 2023/2006 EC on GMP
- Regulation 10/2011 EC and amendments
- Regulation 282/2008 if applicable
- Italian Health Ministry decree nr. 134 of 20 September 2013, if applicable

The above material is produced with PET, masterbatch if coloured and super-cleaned PCR-PET in accordance to regulation 282/2008 EC on recycled plastic materials and articles intended to come into contact with foods.

A technical dossier and application was submitted to EFSA. It has been accepted for evaluation and has been classified under the document reference number, EFSA/CEF/FCM/1905, Reg. Number RECYC077. A positive EFSA opinion was published on November the 10th 2013: <http://www.efsa.europa.eu/en/efsajournal/pub/3397.htm>

The QAS in operation for the recycling process, for which a valid application has been made, conforms to Section B of Annex to amended Regulation (EC) No. 2023/2006 (See Annex II, 282/2008 for amendment details).

Good manufacturing practices includes materials such as bubble and absorbent pads. On the basis of information contained in declarations of compliance from our suppliers, all monomers and additives present in the plastic layers of multi-material components comply with Regulation (EU) No. 10/2011, (EC) 1935/2004, (EC) 2023/2006 as amended. Materials and products not covered by these regulations comply with FDA and BfR.

As required by Regulation (EC) 1935/2004 Article 17, INFIA srl has in place necessary systems, records and procedures to ensure traceability of material and articles at all stages of manufacture in order to facilitate control and recall of defective products. INFIA srl declares to comply also with Articles 3, 11 and 15 of the Regulation (EC) 1935/2004.

Migration test and substances with SML

The substances listed at page 4 of this DoC, according to the EC regulation (EC) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, at the best of our knowledge, may be present and have a Specific Migration Limit.

According to reg.10/2011, annex III table 2, food simulants are not identified for whole fruit and vegetables.

We declare that our products respect overall and specific migrations limits in the following conditions:


SIMULANT	TIME	TEMPERATURE	
		Global	Specific
A - Ethanol 10 %v/v	10 days	40°C	60°C
B - Acetic acid 3 %w/v	10 days	40°C	60°C

This declaration is supported by analysis, worst case calculations and by declaration of compliance issued by our suppliers.

There could be the presence of some substances ("dual use") legislated by EC regulation 1333/2008 and 1334/2008 and subsequent updates and amendments. According to experimental data and/or calculations, these substances are in accordance with the provisions of regulation 10/2011 EC art. 11 par. 3, letter a) and b). The utilizer of the food contact material has the responsibility of let us know about any restriction concerning the composition (additives or aroma) of the food product that has to be packed.

Specification of use - Types of food



According to reg.10/2011, annex III table 2, the following reference number of food category are identified:

	Reference Number	Description of food	Food simulants
	04	Fruit, vegetables and products thereof	-
	04.01	Whole fruit, fresh or chilled, unpeeled	-
	04.04	Whole vegetables, fresh or chilled, unpeeled	-

Specification of use - Foreseeable condition of use

According to Reg. EU 10/2011, annex V, chapter 2, table 1 and paragraph 2.1.4 carrying out specific migration tests for 10 day at 60°C the expected contact condition is: any long term storage greater than 30 days at room temperature or below.

Family range listed above is not suitable for microwave or traditional oven cooking.

	
<u>Do not use in microwave oven</u>	<u>Do not use in traditional, infrared or multipurpose oven</u>

Surface to volume ratio

Due to the heterogeneity of fruit and vegetable density (stone fruits, grapes, berries...) the conventional surface area/volume ratio of 6 dm² per kg of food has been considered. It is impracticable to estimate the relationship between the surface area of such punnets and the quantity of food in contact therewith.

Additional information

Non Intentionally Added Substances (NIAS):

INFIA srl carry out screening tests at least annually to determine the presence and levels of Non Intentionally Added Substances (NIAS) in the products.

The following substances are not used, at the best of our knowledge, during the manufacture of the food contact products:

BADGE, NODGE, BFDGE

Latex



BPA

Chlorofluorohydrocarbons (CFCs) and halogens

Primary Aromatic Amines

The recipient should pay particular attention to any change in the packaged product, its intended use and also to any modification in the material's processing conditions and make sure that the contents and packaging are compatible, as directed in this declaration .

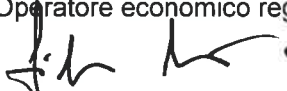
This certificate is only valid when the product is used in normal and foreseeable conditions provided, that the handling and storage conditions are also appropriate for preservation of the material's specific characteristics.


Storage in adequate dry and clean warehouse	
Attention: do not expose to direct sunlight and heat sources	

The use in industrial or commercial application of the material described in this statement does not preclude an assessment of compliance with the current legislation and of the technological suitability for the intended use.

The document is valid from the date below and will be substituted if any change will occur in the formulation of the product or in the legislation applicable. Anyway, it has expiration date of 12 months.

Data 26/07/2017

Firma Operatore economico reg. 1935/2004

INFIA S.R.L.
 Società con socio unico
Montaguti Giuseppe
 Amministratore Delegato

Firma Responsabile Qualità
 Riccardo Zoffoli 

List of authorized substances with SML and SML (T) according to ANNEX I of reg. UE 10/2011.

Dual use additives present in EC reg.1333/2008, EC reg. 1334/2008 and amendments are identified with E number.

Punnets, lids and kit line in PET:

Substance Name	Ref. No	CAS No	SML [mg/kg]
Ethylene glycol	16990	0000107-21-1	SML(T) = 30 mg/kg
Diethyleneglycol	13326	0000111-46-6	SML(T) = 30 mg/kg
Antimony	35760	0001309-64-4	SML = 0,04 mg/kg
Isophthalic acid	19150	0000121-91-5	SML(T) = 5 mg/kg
Terephthalic acid	24910	0000100-21-0	SML(T) = 7,5 mg/kg
Acetaldehyde	10060	0000075-07-0	SML(T) = 6 mg/kg
Cobalt	79987	1002-88-6	SML = 0,05 mg/kg
polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C8-C22) alcohols	77708	-	SML = 1,8 mg/kg

Bubble Pad (if present) for whole fruit:

Substance Name	Ref. No	CAS No	mg/kg
Zinc	0	-	SML =5 mg/kg
acetic acid, vinyl ester	10120	0000108-05-4	SML =12 mg/kg
Acrylic acid, methyl ester	11710	0000096-33-3	SML =6 mg/kg
Caprolactam	14200	0000105-60-2	SML =15 mg/kg
1-hexene	18820	0000592-41-6	SML =3 mg/kg
Maleic anhydride	19960	0000108-31-6	SML =30 mg/kg
1-octene	22660	0000111-66-0	SML =15 mg/kg
N, N-bis(2-hydroxyethyl) alkyl (C8-C18) amine	39090	-	SML =5 mg/kg
boric acid	40320	0010043-35-3	SML =6 mg/kg
cis-1,2-cyclohexanedicarboxylic acid, calcium salt			
3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	46880	0065140-91-2	SML =6 mg/kg
glycerides, castor-oil mono-, hydrogenated, acetates	55910	0736150-63-3	SML =60 mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	68320	0002082-79-3	SML =6 mg/kg
Phosphorous acid, tris (nonyl-and/or dinonylphenyl) ester	74400	-	SML =30 mg/kg
phthalic acid, bis(2-ethylhexyl) ester	74640	0000117-81-7	SML =1,5 mg/kg
phthalic acid, dibutyl ester	74880	0000084-74-2	SML =0,3 mg/kg
Zinc Oxide	96240	0001314-13-2	SML (T) = 5 mg/kg
Zinc Stearate	99558		SML (T) = 5 mg/kg
2-methyl-1,3-butadiene	19243	000078-79-5	Not detectable or 1 mg/kg in the finisch product
Butadiene	13630	000106-99-0	Not detectable or 1 mg/kg in the finisch product
2,4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	40000	000991-84-4	SML =30 mg/kg
DUAL USE ADDITIVES			
	Ref. No	CAS No	E-number
Sodium, potassium and calcium salts of fatty acids	30610		E471 - E470a - E470 b
Citric Acid	14680 - 44160	0000077-92-9	E330- E333
2,6-di-tert-butyl-p-cresol	46640	0000128-37-0	E 321 - SML = 3 mg/kg
Kaolin	62720		-
Phosphoric Acid	72640	0007664-38-2	E 338 - E339 - E341 iii
Polydimethylsiloxane (Mw > 6800 Da)	76721	0063148-62-9	E 900
Polyethyleneglycol sorbitan monolaurate	79040	0009005-64-5	E 432
Silicon dioxide	86240	0007631-86-9	E 551
stearic acid	89040	0000057-11-4	E 570 - E 572
Talc	92080	0014807-96-6	E 553 b
Calcium Stearate	89040	0000057-11-4	E 572
Hydrocarbonic Resins	Listed in paragraph FDA 175.105		-

Absorbent pad (if present) for whole fruit:

Substance Name	Ref. No	CAS No	mg/kg
zinc oxide (only in white)	96240	0001314-13-2	SML(T) = 5 mg/kg
4,4'-thiobis(6-tert-butyl-3-methylphenol)	92800	0000096-69-5	SML = 0,48 mg/kg
Zinc	-	0000557-05-1	SML(T) = 5 mg/kg
1-hexene	18820	0000592-41-6	SML = 3 mg/kg
acrylic acid, tert-butyl ester	10840	0001663-39-4	SML = 6 mg/kg
acrylic acid, n-butyl ester	10780	0000141-32-2	SML = 6 mg/kg
bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite	38820	0026741-53-7	SML = 6 mg/kg
maleic anhydride	19960	0000108-31-6	SML = 30 mg/kg
acrylic acid	10690	79-10-7	SML = 6 mg/kg
octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	68320	0002082-79-3	SML = 6 mg/kg
vinylidene fluoride	26140	75-38-7	SML = 5 mg/kg
Copper	-	7440-50-8	SML = 5 mg/kg
Iron	-	7439-89-6	SML = 48 mg/kg
2,4,6-triamino-1,3,5-triazine	19975 25420 93720	108-78-1	SML = 30 mg/kg
hexafluoropropylene	18430	116-15-4	SML = ND mg/kg
3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	46880	65140-91-2	SML = 6 mg/kg
2-methyl-1,3-butadiene	19243	000078-79-5	Not detectable or 1 mg/kg in the finisch product
Butadiene	13630	000106-99-0	Not detectable or 1 mg/kg in the finisch product
phosphorous acid, tris(nonyl-and/or dinonylphenyl) ester	74400	-	SML = 30 mg/kg
DUAL USE ADDITIVES			
	Ref. No	CAS No	E-number
Calcium carbonate	42500		E 170
TiO ₂	93440	0013463-67-7	E 171
Iron oxide	62240	0001332-37-2	E 172
Malic acid	19965 65020	0006915-15-7	E 296
acids, C2-C24, aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)	30610	-	E 470a
Calcium oxide	41520	0001305-78-8	E 529
SiO ₂	86240	0007631-86-9	E 551
Talc	92080	0014807-96-6	E 553 b
Stearic Acid	24550 81840	0000057-11-4	E 570 E 572
1,2-propanediol	23740 81840	0000057-55-6	E 1520
Hydrocarbonic Resins	Listed in paragraph FDA 175.105		-

