

LIMITED LIABILITY COMPANY **BIAXPLEN**(BIAXPLEN LLC)

To whom it may concern

Revised: 21 October 2019

DECLARATION OF COMPLIANCE According to Regulation (EU) 10/2011

Product: BIAXPLEN HASL - Transparent, antifog, both side corona treated BOPP film, for high quality rotogravure and flexographic printing for the production of packaging for salads and vegetables

European Union Regulations

We can confirm that the mentioned above product complies with food contact requirements of Regulation (EU) No 10/2011 (and related updates and amendments including Regulation (EU) 2019/1338), Regulation (EC) No 1935/2004 (and related updates and amendments) and Regulation (EC) No 2023/2006 (and related updates and amendments).

The product may contain the substances subject to a Specific Migration Limit (SML). In order to establish the compliance of the products the ratio of food contact surface area to volume used was 6 dm² per kg of food. Based on testing results and theoretical calculations (worst case) the content of those substances complies with Regulation (EU) No 10/2011.

Ref.№	CAS №	Name of additive	SML mg/kg	SM, mg/kg
1	2	3	4	5
74880	0000084-74-2	Dibutyl phthalate (DBP)	0,30	0,0120
83595	0119345-01-6	Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4- di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl.	18,00	0,0035
38820	0026741-53-7	Bis (2,4-di-tert-butylphenyl) penta erythritol diphosphate	0,60	0,0049
21130	0000080-62-6	Methacrylic acid, methyl ester	6,00	0,0001
39090	0071786-60-2	N,N-bis(2-hydroxyethyl)alkyl(C 8- C 18)amine	1,20	Not detected*
95360	0027676-62-6	1,3,5-tris(3,5-di-tert-butyl-4- hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	5,00	0,0397
55910	0736150-63-3	Glycerides, Castor Oil monohydrogenates, Acetates	60,00	0,0020
74560	0000085-68-7	BBP. Catalyst residue	30,00	0,0050
74640	0000017-81-7	DEHP. Catalyst residue (phthalic acid, bis(2-ethylhexyl) ester))	1,5	0,0049
39090	0071786-60-2	N,N-bis(2-hydroxyethyl)alkyl(C 8- C 18)amine	1,2	0,0005
68320	0002082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4- hydroxyphenyl)propionate	6,0	0,0005

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- (5) Shown specific migration (SM) means content of restricted chemicals in 6 dm 2 of the film. SM of restricted substances was calculated from maximum thickness (40 μ m) which provides the highest possible migration to show that SM value will never be above of SML value.
- * Specific Migration data were obtained as results of tests performed in accredited laboratory (Chelab S.r.l, simulants A, B, D2, 60 C for 10 days).

Dual use additives

According to the information provided by the raw materials suppliers, available till the present moment, some batches that can be used in the production of the mentioned above product may contain the following "dual use" substances:

Code	Name of additive, Synonyms and application.		
E-471	Mono- and diglycerides of fatty acids		
E-470	Calcium Stearate		
E-470a	Sodium, potassium and calcium salts of fatty acids		
E-551	Silicon dioxide		
E-330	Citric acid		

Overall migration of substances

Overall migration tests were performed according to Regulation (EU) No 10/2011 (and related updates and amendments) by using the following food simulants at condition of $40\,^{\circ}\text{C}$ for $10\,\text{days}$ without exceeding the maximum allowed limit:

simulant A: 10% aqueous solution of ethanol simulant B: 3% aqueous solution of acetic acid

simulant D2: vegetable oil

Usage

BOPP film mentioned in this Declaration intended to come in contact with all kind of foodstuffs. Ratio of area of the BOPP film related to mass foodstuffs to be in contact between each other is 6 dm²/kg (film/food). Time and temperature of storage in contact with the foodstuffs is any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/ or heating up to a temperature 100 °C for a maximum of 15 minutes.

Heavy metals

The product complies with requirements of Directive 94/62/CE (and related updates and amendments). The heavy metals cadmium, lead, mercury and chromium VI are not intentionally used for the production of the product. The sum of the cadmium, lead, mercury and chromium VI incidentally present in the product is lower than 100 ppm.

For additional information please contact:

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