

## Declaration of Compliance

### 1. Product Manufacturer - Plastchim-T AD

Seat:

Bulgaria, Tervel 9450, 97 Khan Asparuh Str

Production of BOPP:

Bulgaria, 9154 Aksakovo, 21 Dobrudza Str;

Bulgaria, 9160, Devnya, Industrial Zone South

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Producer of BOPP films for food packaging types: FXA, FXAA, FXAAB, FXAS, FXC, FXCAF, FXCB, FXCF, FXCFM, FXCFMB, FXCFMLS, FXCFMULS, FXCHF, FXCHM, FXCL, FXCLS, FXCM, FXCMB, FXCMLS, FXCMT, FXCMTB, FXCMTS, FXCHMULS, FXCMULS, FXCP, FXCU, FXCULST, FXCW, FXCWB, FXCWLS, FXCWP, FXCWPLS, FXCWPR, FXP, FXPA, FXPAB, FXPB, FXPBR, FXPF, FXPFB, FXPFM, FXPFMB, FXPL, FXPLA, FXPLF, FXPM, FXPMB, FXPMT, FXPMTS, FXPR, FXPS, FXPU, FXPWP, FXS, FXSF, FXT, FXWD, FXWDM, FXWL, FXWLB, FXWLFMB, FXWLMB, FXWPUS.

### 2. Used materials for production of BOPP films:

- PP homopolymer (types mostly used: Moplen HP 525J; Moplen HP 526J; Ecolen HF 14K; Repol H 034SG; Tatren HF 3 22; APC PP 1104K; Sabic PP521 P)
- PP copolymer, PP terpolymer (types mostly used: Adsyl 5C37F; Adsyl 5C37F ST; Eltex P KS 350; Eltex P KS 357)
- Additives for regulation of Coefficient of Friction, electrostatic characteristics, optical properties etc. (types mostly used: : Constab SAT 04509; Schulman FASPS 2950 W; Schulman PF 97 NTS; Ampacet COEXAS 33; White CC 18160 PP; Ampacet White 96)
- All used materials are suitable for food contact and there is no presence of functional barrier.

### 3. This declaration is Edition 16 issued on 19 January 2023

### 4. Regulatory Compliance

We declare and confirm that all types of BOPP films, produced by Plastchim-T AD meet the requirements listed in regulations as follows:

#### 4.1. Food Contact Regulations

- Commission Regulation (EU) № 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food amended by Regulations №1245/2020, №2019/1338, №2019/37, №2018/831, №2018/213; № 2018/79, № 2017/752, №2016/1416, №2015/174, №202/2014, №1183/2012, №1282/2011 and №321/2011 applicable to intermediate materials (e.g. a film, requiring further processing/re-formulation steps to become a “finished” material or article).

According to the information received from our suppliers monomers and additives used to produce PP homopolymers, PP copolymers, PP terpolymers and additives used to produce this BOPP films are listed in the Union List of Authorized Substances of Regulation (EU) No 10/2011 and its subsequent amendments (ANNEX I).

This products contains dual use additives. The information provided concerning additives which are also food additives and flavouring is based on our current knowledge.

Depending on the applications, the possible impact of dual use additives should be considered by the manufacturer of the finished plastic food contact material or article, as well as the industrial food packers.

There are NO restrictions (SML) specified by Regulation (EU) No 10/2011 as amended, for the PP homopolymers, PP copolymers, PP terpolymers and additives used for production of these BOPP films. However, this products can contains one or more process aids and/or traces of a substance which is regulated with a specific migration limit in EU (Commission Regulation 10/2011; Annex II). Migration tests showed a migration level significantly below the SML, thus exceeding this SML under foreseeable conditions of use involving food contact is not expected.

Non-Intentionally Added Substances (NIAS) have been risk assessed in these products in accordance with Article 19 of European Food Contact Regulation (EU) No 10/2011 and comply with Article 3.1 (a) of Framework Regulation 1935/2004/EC.

To fully comply with food regulation (EU) No 10/2011, the overall migration (OML) from the finished plastic food contact material or article to food can be no greater than 10 mg/dm<sup>2</sup>, with the exception for plastic materials and articles intended to contact infant or young child food (60 mg of total constituents released per kg of food simulant). The OML and SMLs (when applicable) should be determined according to the requirements specified in Regulation (EU) No 10/2011 and subsequent amendments. A representative sample of these BOPP films was tested with food simulants, per general conditions of use as established in Regulation (EU) No 10/2011 and its amendments, and the experiments have shown that the OML and SML were not exceeded.

These test results are only valid for orientation purposes and must not be used to confirm legal compliance of the finished plastic food contact material or article.

Verification of compliance with the specific migration limit of Aluminum, Ammonium, Antimony, Arsenic, Barium, Cadmium, Calcium, Chromium, Cobalt, Copper, Europium, Gadolinium, Iron, Lanthanum, Lead, Lithium, Magnesium, Manganese, Mercury, Nickel, Potassium, Sodium, Terbium, Zinc mentioned in paragraph 1 of Annex II of Regulation (EU) No 10/2011 and amended by Regulation (EU) 2020/1245 of 2 September 2020, has been carried out in food simulants set out in Annex III in accordance with the rules set out in Chapter 2 of Annex V of Regulation (EU) No 10/2011. The experiments have shown that these BOPP films complies with the requirements for food contact and is suitable as a material for the manufacture of articles intended to come into contact with food and food packaging.

All the obtained results are only valid for orientation purposes and must not be used to confirm legal compliance of the finished plastic food contact material or article, thus the migration of substances from final products should be tested separately.

Compliance with the OML and SML of the finished plastic food contact material or article, as set by Regulation (EU) No 10/2011, are the responsibility of the manufacturer of the finished plastic food contact material or article, as well as the industrial food packers.

We remind you that the manufacturer of the finished food contact material or article must verify that the finished material or article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food.

- Regulation (EC) No 1935/2004 (Framework) of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. Representative sample of the main BOPP film types was tested with food simulants. The samples were tested according to ISO 13302:2003. The results showed that the BOPP films complies with the requirements of Regulation (EC) 1935/2004, Article 3 and not to bring about deterioration in the organoleptic characteristics of the food it comes into contact with regarding different types of food.

Detailed information can be provided upon customer's request.

- Commission regulation № 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food amended by Regulation № 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and Commission Regulation (EC) No. 2015/1906 of 22 October 2015 on recycled plastic materials and articles intended to come into contact with foods
- Commission Regulation (EC) No. 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food
- Plastics Directive 2002/72/EC and its later amendments 2004/1/EC, 2004/19/EC, 2005/79/EC, 2007/19/EC, 2008/39/EC, 975/2009/EC, 2010/169/EC and/or the Synoptic Document
- **Italian Regulations:**  
D.M. 21/03/1973 and following revisions and amendments,  
DPR 777/82 and following revisions and amendments, UNI 13430/2005
- **Germany Regulations**  
BfR Recommendations: In accordance with details of our raw material suppliers, this product complies with the BfR Recommendations VII. Polypropylene as of 01.06.2019.
- **Canadian Food and Drug Regulations**  
Division 23 – Food Packaging Materials
- **Switzerland Regulation**  
BGVO 817.023.21 of 23<sup>rd</sup> November 2005, and revised version of the Ordinance on Materials and Articles in contact with food (817.023.21), which came into force on 1<sup>st</sup> May 2017 and all subsequent amendments including Annex 10, Edition 2.1, entry into force on 1 December 2020.  
This product contains less than 3% VOC's of the substances in the positive lists of the Switzerland Regulations "VOC-LENKUNGSABGABE"
- **US Food and Drug Administration (FDA)**  
We declare that our films meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520 for Olefin polymers. We confirm that the production of our BOPP films that we supply to the customers are made only from the materials approved by FDA. All components comply with the US Food, Drug and Cosmetic Act of 1958 and applicable indirect food additive regulations of the United States of America as set out in the Code of Federal Regulations of the US Food and Drug Administration (FDA), under title 21 with sections as:  
 174.5  
 178.3130  
 178.3860  
 178.2010  
 182.1711  
 184.1033  
 184.1324

According to the information received from our suppliers the base resins in this products meet the FDA requirements in 21 CFR 177.1520 (a) (1)(i) and (c)1.1a.

According to the information received from our suppliers this product may contain adjuvant substances that may be safely used in polymers used for the manufacture of articles that come into direct contact with food. According to information, these substances used in this product meet the requirements of their respective FDA regulations, FCNs, and 21 CFR 177.1520(b).

This products meet the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2, and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1

It is the responsibility of the converter or food packer to control that the final packaging complies with the requirements of the intended and foreseeable conditions of use.

- **MERCOSUR**

According to the information received from our raw material suppliers the base resins used in production of our BOPP films complies with the relevant requirements of:

- GMC Resolution No. 03/1992 of April 1st 1992, which establishes the general criteria and classification of materials for packaging and equipment in contact with food.
- GMC Resolution No 02/2012 of April 19th 2012, which provides a positive list of monomers, other starting substances and polymers authorized for the manufacture of plastic packaging and equipment that come into contact with food.
- GMC Resolution No 39/2019 of July 15th 2019, which provides a positive list of additives for plastic materials for the preparation of plastic materials and polymeric coatings in contact with food.

According to the information received from our raw material suppliers the monomers and additives used to produce the base resin used in production of our BOPP films are listed in Part I: “List of monomers and other authorized starting substances” of GMC Resolution No 02/1992 and in the “Positive list of additives for plastic materials for the preparation of plastic materials and polymeric coatings in contact with food” of GMC Resolution No 39/2019 respectively.

According to the information received from our raw material suppliers our BOPP films may contain one or more components with Specific Migration Limit (SML).

In order to guarantee the compliance with the Resolutions mentioned above, it is the responsibility of the manufacturer of the finished plastic food contact material to analyze it concerning total migration limit and such limit must be less than 50 mg/kg or 8 mg/dm<sup>2</sup>.

- **PR China**

According to the information received from our suppliers the additives and PP Homopolymers and terpolymers, used for the production of our BOPP films do not contains any substances which are regulated with a restriction in their use. All intentionally added substances contain only substances that are subject to PRC National regulating standards and are listed on this standards as follow:

GB 4806.1-2016 General safety requirements for food contact material and articles;  
 GB9685-2016 Standard for uses of additives in food contact materials and articles; GB 4806.7-2016 National Food Safety Standard for Plastic Materials and Articles in Contact with Foodstuffs; GB 4806.6-2016 National Food Safety Standard for Resins Used to Make Plastics in Contact with Foodstuffs - Appendix A - 74 Propylene homopolymer

- **Japan**

**Food Contact Positive Lists by Japan’s Ministry of Health, Labour and Welfare (MHLW) issued on April 28th, 2020 and effective on June 1st, 2020**

According to the information received from our raw material suppliers the base resin used for production of homopolymers, copolymers, terpolymers and additives, used for the production of our BOPP films are listed in the Positive List of Base Polymers.

The additive/s used in production of homopolymers, copolymers, terpolymers and additives, used for the production of our BOPP films are listed in the Positive List of Additives authorized for use in the Base Resin of this product.

#### **4.2. GMP**

In accordance with Regulation 2023/2006/EC as amended by Commission Regulation (EC) No. 282/2008 of 27 March 2008 and Commission Regulation (EC) No. 2015/1906 of 22 October 2015 Plastchim-T AD declares that the company is in compliance with general rules on good manufacturing practice (GMP).

#### **4.3. California Safe Drinking Water and Toxic Enforcement Act of 1986**

Based on certification from our resin and additive suppliers, we certifies that all BOPP films do not contain any cancer causing or reproductive toxicity chemicals. We certify that during the

production of our films, we do not use or intentionally add into them any of the substances as restricted on the California Proposition 65 List of Chemicals and its subsequent amendments up to the Chemicals Listed Effective Feb 25, 2022 pursuant to the California Safe Drinking Water and Toxic Enforcement Act of 1986 (also known as California Proposition 65)

#### **4.4. Conflict minerals**

Dodd-Frank Wall Street Reform and Consumer Protection Act - September, 2010

#### **4.5. Allergen Statements**

The food ingredients listed in Annex II of Regulation (EU) No 1169/2011, are not used in the manufacture of or formulation of these products. However, this product has not been tested for these substances.

#### **4.6. Toy safety**

This product does not contain restricted chemical substances and heavy metal elements over its limit threshold regulated by Toy safety Directive 2009/48/EC and its later amendments 2012/7/EC, 2014/79/EC, 2014/81/EC, 2014/84/EC

#### **4.7. Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS)**

RoHS Regulation refers to electrical and electronic equipment and not specifically to plastic materials. However, based on the available documentation from raw materials suppliers, this product complies with the requirements of the Directives 2002/95/EC, Directive 2011/65/EU and Directive 2015/863/EU as amended, concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl)phthalate (DEHP), butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP).

#### **4.8. WEEE, Directive 2012/19/EU**

We do not intentionally add substances (As, Hg, PCB, PCT, CFC, HCFC, HFC, Brominated Flame retardants ) restricted by 2012/19/EC.

#### **4.9. REACH**

**Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)**

Plastchim-T AD does not need to register or pre-register its own films. Under the EC Regulation REACH these products are classified as a preparation. Our suppliers confirm that all substances of this preparation are compliant to the pre-registration requirements of REACH, and they will have the intentions to proceed with the registration of these substances, or to procure substances only from suppliers from which confirmation has been received that the suppliers are aware of their REACH requirements, that they have pre-registered and/or will timely register their substances, and that they will supply the relevant Safety Data Sheets (SDS) with REACH registration numbers as soon as the registrations occur.

We declare that

- We don't intentionally use or add substances mentioned in Annex XIV and Annex XVII of Regulation (EC) No 1907/2006 (REACH), including last amendments – Commission Regulation (EU) 2018/35 of 10.01.2018.
- We don't intentionally use or add substances of very high concern (SVHC) published on the latest version of [REACH Candidate List](#) from 17 January 2023.

According to the information received from our suppliers of additives, PP Homopolymers and terpolymers Plastchim-T AD can state that according Regulation № 453/2010/EC amending 1907/2006/EC (REACH) we do not intentionally use or add phthalates (DEHP, DBP, BBP, DIBP, DIDP, DINP, DMP, DnHP, DnOP, DEP, DMEP) as polymer additives when we produce these films.

#### **4.10. Epoxy derivatives – Regulation (EC) No 1895/2005**

Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.

- BADGE – (2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxylpropyl)),
- BFDGE – (bis(hydroxyphenyl)methane bis(2,3-epoxylpropyl)),
- NOGE – (novolac dlycidyl),

are not intentionally added to these products.

#### **4.11. Directive 94/62/EC**

Packaging and Packaging Waste Directive, amended by Regulation (EC) №1882/2003, Directive № 2004/12/EC, Directive № 2005/20/EC, Regulation (EC) №219/2009, Directive № 2013/2 EU, Directive (EU) № 2015/720, Directive (EU) № 2018/852 for heavy metals present in the packaging and their release into the environment; dangerous substances present in the packaging and their release into the environment.

#### **4.12. Heavy Metals**

No heavy metals (i.e., antimony, arsenic, barium, cadmium, chromium, Hexavalent chromium, lead, mercury, selenium, or silver) are purposely added to these products in quantities that could violate any governmental guidelines.

#### **4.13. Directive 89/107/EC repealed by Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives**

Regarding Annex 1 we don't use following functional classes of food additives:

Colour	Modified starch
Preservative	Sweetener
Anti-oxidant	Raising agent
Emulsifier	Anti-foaming agent
Emulsifying salt	Glazing agent (3)
Thickener	Flour treatment agent
Gelling agent	Firming agent
Stabilizer (1)	Humectant
Flavour enhancer	Sequestrant (4)
Acid	Enzyme (4) (5)
Acidity regulator (2)	Bulking agent
Anti-caking agent	Foaming agents
Carriers	Propellant gas and Packaging gas

#### **4.14. Perfluorooctanoic acid and Perfluorooctane sulfonate – Directive 2006/122/EC**

The manufacture of this product does not involve addition of perfluorooctanoic acid (PFOA), and perfluorooctane sulfonate (PFOS)

#### **4.15. Cosmetic - Regulation (EC) No 1223/2009**

We, hereby, inform you that the prohibited substances in the list of Regulation (EC) No 1223/2009 are not used or added in this product.

#### **4.16. Phthalates**

Phthalates are not used as plasticizers when this product is manufactured. This grade may contain trace levels of one phthalate because of catalyst residues and it is expected not more than 10 ppm. For more detailed information please contact with sales department representative.

#### **4.17. Regulation (EC) No 1334/2008**

Regarding Directive 88/388/EEC, Repealed by Regulation (EC) No 1334/2008 of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC – we don't use any "flavourings" in our products.

#### **4.18. Regulation (EU) No 528/2012**

Regarding Regulation (EU) No 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products we don't use any biocidal products in our films.

#### **4.19. Regulation (EC) No 1107/2009**

Regarding Regulation (EC) No 1107/2009 of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC we don't use any plant protection products in our films.

#### 4.20. Stockholm Convention

Regarding Regulation (EC) No850/2004 of 29 April 2004 on persistent organic pollutant and amending Directive 79/117/EEC, repealed by Regulation (EU) 2019/1021 of 20 June 2019 on persistent organic pollutants we don't use any substances listed in Annexes I, II, III and IV

#### 4.21 Ozone-depleting substances

Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer

The ozone-depleting substances (ODS), listed in the Annexes I & II of the Regulation ( EC ) No1005/2009 of 16 September 2009, are not intentionally used in the formulation of this products.

#### 4.22 Directive (EU) 2019/904

Regarding Directive (EU) 2019/904 of 5 June 2019 on the reduction of the impact of certain plastic products on the environment and the implementing national regulations of the Republic of Bulgaria the BOPP films produced by Plasschm – T AD are not listed in the Annex and are not covered by the Directive because they do not meet the requirements described in the Product description and criteria in the Directive.

The Directive may apply to some single-use plastic packaging products produced after further processing of BOPP films supplied by Plastchim – T AD. For the information of our customers, we declare that all BOPP films of Plastchim – T AD are made of 100% plastic and can pollute the environment with improper disposal after use. However, with proper disposal and collection, these products are 100% recyclable.

### 5. Migration Limits

During the production of BOPP films we do not intentionally add substances, that exceed SM limits according Regulation № 10/2011/EC (Annex I, Annex II Substances);

#### 5.1. SML substances

During the production we use additives that are in conformity (regarding producer documents) to this Framework Regulation (1935/2004/EC) and Regulation 10/2011/EC with amendments. Also we declare that according our calculations (assuming that 1 kg. of food is packaged with 6 dm<sup>2</sup> of film) we do not exceed SM limits of the substances with the following restrictions for none of the film types we produce for any of the thicknesses produced. The worst-case calculation of maximum possible migration of SML substances was made in order to cover all thicknesses of the produced BOPP films from 15µm to 50 µm.

Table 1

FCM substance №	Ref №	CAS №	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML (mg/kg food)	SML(T) (mg/kg food) group restriction №	Max. SM (mg/kg food) (calculated)
661	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	yes	No	yes	5		< 0.265
760	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	yes	no	no	18		< 0.265

779	39815	0182121-12-6	9,9-bis(methoxymethyl)fluorene	yes	no	yes	0.05		<0.005
433	68320	0002082- 79-3	octadecyl 3-(3,5-di-tert-butyl-4- hydroxyphenyl ) propionate	yes	no	yes	6		< 0.265
19	39090*	-	N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine	yes	no	no		(7)	<1.06

\* – Not contained in metallized films and films intended for metallization

### 5.2. Dual-use additives:

Some of our products may contain one or more food additives as defined in Regulation 10/2011/EC such as:

Table 2

FCM substance №	Ref №	CAS №	Substance name	SML	Max. content (calculated)
-	-	-	Calcium salts of fatty acids	-	0.04%
-	-	471-34-1	Calcium carbonate E170 (used only for pearl white films)	-	12%
504	86240	7631-86-9	Synthetic Silica (E551)	-	0.005%
610	93440	13463-67-7	TiO <sub>2</sub> (used only for white films) E171	-	7%

We declare also that none of the ingredients used during the production of the aforementioned films contain substances that exceed the limits of [Regulation 10/2011/EC](#).

**For more detailed information please contact with sales department representative.**

## 6. Experimental data from migration tests and NIAS risk assessment

To the best of our knowledge and based on the available information from raw materials suppliers, we identify possible predicted NIAS, being reaction/breakdown products formed from the IAS and base materials or contaminations as: Formaldehyde, PAA, 1-octen, 4-metyl-1-penten and metals.

A representative sample of these BOPP films was tested with food simulants, per general conditions of use as established in Regulation (EU) No 10/2011 and its amendments, and the experiments have shown that the OML and SML were not exceeded.

These test results are only valid for orientation purposes and must not be used to confirm legal compliance of the finished plastic food contact material or article.

Below is presented adequate information related to the substances that are a subject to restriction in food, obtained by experimental data with migration tests, carried out according to Regulation 10/2011/EC (simulants A, B, D2 (substitute 95% ethanol) and E at the condition of 10 days at 60°C or 10 days at 40°C.

**Detailed information can be provided upon customer's request.**

Table 3

№	Overall migration of low molecular substances	Units	Measured value	OML	Test conditions
1.	Migration of low molecular substances	mg/dm <sup>2</sup>	ND LOD=0.8	10	10 days 60 °C with 10% ethanol
2.	Migration of low molecular substances	mg/dm <sup>2</sup>	ND LOD=0.8	10	10 days 60 °C with 3% acetic acid
3.	Migration of low molecular substances	mg/dm <sup>2</sup>	ND LOD=1.0	10	10 days 60 °C with vegetable oil (95% ethanol)
4.	Migration of low molecular substances	mg/dm <sup>2</sup>	< 0.1	10	10 days 40 °C with MPPO



№	Specific migration – Name of the index	Units	Measured value	SML	Test conditions
1.	Specific migration - formaldehyde	mg/kg	< 0.005	15	10 days 40 °C with 10% ethanol
2.	Specific migration - formaldehyde	mg/kg	< 0.009	15	10 days 40 °C with 3% acetic acid
3.	Specific migration - formaldehyde	mg/kg	< 0.16	15	10 days 40 °C with vegetable oil (95% ethanol)
4.	Specific migration – primary aromatic amines	mg/kg	< 0.01	< 0.01	10 days 40 °C with 10% ethanol
5.	Specific migration – primary aromatic amines	mg/kg	ND LOD=0,00015	< 0.01	10 days 60 °C with 3% acetic acid
6.	Specific migration – primary aromatic amines	mg/kg	< 0.01	< 0.01	10 days 40 °C with 95% ethanol
7.	Specific migration - metals	mg/kg	Ba <0.003 Co <0.0005 Cu – 0.01 Fe – 0.022 Li < 0.001 Mn < 0.003 Zn < 0.005 Al < 0.005 Ni – 0.002	Ba - 1 Co – 0.05 Cu – 5 Fe - 48 Li – 0.6 Mn – 0.6 Zn – 5 Al – 1.0 Ni – 0.02	10 days 40 °C with 10% ethanol
8.	Specific migration - metals	mg/kg	Ba <0.012 Co – ND LOD=0.00001 Cu < 0.0007 Fe < 0.02 Li < 0.00051 Mn < 0.0007 Zn < 0.02 Al <0.02 Ni – 0.00024 Sb – ND LOD=0.00005 As – 0.00032 Cd - ND LOD=0.00001 Ca – 0.3 Cr <0.0007  Eu – ND LOD=0.00001 Gd – ND LOD=0.00001 La – ND LOD=0.00001 Pb – 0.0060  Mg – ND LOD=0.1 Hg – ND LOD=0.00001 K <0.3 Na – 0.58 Tb – ND LOD=0.00001 Ammonium <0.3	Ba - 1 Co – 0.05  Cu – 5 Fe - 48 Li – 0.6 Mn – 0.6 Zn – 5 Al – 1.0 Ni – 0.02 Sb – 0.04 ND (LOD=0.01) ND (LOD=0.002) - ND (LOD=0.002) Eu – 0.05  Gd – 0.05  La – 0.05  ND (LD=0.01) -  ND (LOD=0.01) - - ND (LOD=0.05) -	10 days 60 °C with 3% acetic acid
9.	Specific migration - metals	mg/kg	Ba <0.003 Co <0.0005 Cu – 0.01 Fe – 0.022 Li < 0.001 Mn < 0.003 Zn < 0.005	Ba - 1 Co – 0.05 Cu – 5 Fe - 48 Li – 0.6 Mn – 0.6 Zn – 5	10 days 40 °C with vegetable oil (95% ethanol)

			Al < 0.005 Ni – 0.002	Al – 1.0 Ni – 0.02	
10.	Specific migration - formaldehyde	mg/kg	< 1.5	15	10 days 40 °C with MPPO
11.	Specific migration - metals	mg/kg	Ba < 0.1 Co < 0.01 Cu < 0.015 Fe < 0.05 Li < 0.008 Mn < 0.015 Zn < 0.015	Ba - 1 Co – 0.05 Cu – 5 Fe - 48 Li – 0.6 Mn – 0.6 Zn – 5	10 days 40 °C with MPPO
12.	Specific migration - 4-metyl-1-penten	mg/kg	<0.005	0,05	10 days 40 °C with MPPO
13.	Specific migration - 1- octene	mg/kg	<0.9	15	10 days 40 °C with MPPO
14.	Specific migration - primary aromatic amines	mg/kg	<0.01	<0.01	10days 40 °C with MPPO

## 7. Specifications on the use of the BOPP:

BOPP films can be in contact with all types of food;

BOPP films are tested for contact with all types of food regarding Methods described in Annex III in Regulation 10/2011/EC (Table 1, List of food simulants). Testing for 10 days at 60 °C shall cover long term storage above 6 months at room temperature and below including hot-fill and/or heating up to 70 °C for up to 2 hours, and/or heating up to 100 °C for up to 15 minutes.

It is not recommended to use the BOPP films in temperatures higher than 70<sup>0</sup>C for more than two hours or up to 100<sup>0</sup>C for more than 15 minutes.

There is no any limitation for the duration of the contact with food at room temperature and below;

Regulation 10/2011/EC has not issued any specific regulation on food packaging for microwave use. If the film is in contact with fatty based foods it is possible to have overheating temperatures which can be above the melting point of the polypropylene film and cause non-compliance through breakdown. We recommend using BOPP films with temperatures below 110<sup>0</sup>C;

BOPP film is made of materials, which can not be filled in and for which it is practically impossible to establish the ratio of food contact surface area to the quantity of the food, which is in contact.

**All data in this Declaration are in accordance with the assumption that 1 kg of food is packaged with 6 dm<sup>2</sup> of film.**

## 8. Traceability

We confirm that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet relevant requirements laid down in this Regulation 10/2011/EC and Regulation (EC) No 1935/2004 and Plastchim-t AD has an appropriate system which allows the full traceability of the rolls to the raw material.

## 9. Other Restrictions

According to the information received from our suppliers the additives and PP Homopolymers and terpolymers, used for the production of said films do not contain any genetically modified organisms (GMO), palm oil, substances derived from rice, bamboo, corn or other similar constituents, NANO materials, Carcinogen, Mutagenic, Genotoxic or Toxic to the reproduction materials and Endocrine Disruptors. Plastchim-T AD can state also that we do not intentionally use or add genetically modified organisms (GMO), palm oil, substances derived from rice, bamboo, corn or other similar constituents, NANO materials, Carcinogen, Mutagenic, Genotoxic or Toxic to the reproduction materials and Endocrine Disruptors.

Some additive in this products could derive from animal sources. Our suppliers have stated that their tallow derived additive is obtained exclusively by class 3 animal by-products and by fats coming from BSE free countries (classified in accordance with Article 5(2) of Regulation 999/2001/EC and its

amendments), according to European Regulations 1069/2009/EC and (EU) No 142/2011, as amended, on health rules as regards animal by-products and derived products not intended on human consumption. In addition, our suppliers declared that the manufacture of tallow derived materials fulfils the requirements laid down in the “Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products EMA/410/01 rev.3”.

We do not have information from our raw material suppliers that any of them intentionally uses any substance listed in ECHAs Endocrine disruptor assessment list. We also do not intentionally use any of these substances, so we do not expect them to be contained in our products. However, our products have not been tested.

We do not have information from our raw material suppliers that any of them intentionally uses any substance listed in ANSES List of Substances with potential endocrine disrupting activity. We also do not intentionally use any of these substances, so we do not expect them to be contained in our products. However, our products have not been tested.

We do not intentionally use or add substances harmful to human health and the environment listed in the SIN list that have been identified by International Chemical Secretariat (ChemSec) in the last version of the SIN list/Food contact materials – November 2019.

We do not have information from our raw material suppliers that any of them intentionally uses any substance listed in the OSPAR List of Chemicals for Priority Action and the OSPAR List of Substances of Possible Concern. We also do not intentionally use any of these substances, so we do not expect them to be contained in our products. However, our products have not been tested.

We do not have information from our raw material suppliers that any of them intentionally uses any chemical substances listed in the IARC and NTP Lists. We also do not intentionally use any of these substances, so we do not expect them to be contained in our products. However, our products have not been tested.

No treatment of products or raw materials with ionizing radiation for sterilization or other purposes is applied in the production of the BOPP films supplied by Plastchim – T AD.

## 10. Other Non-use substances

According to the information received from our suppliers none of the following substances are used in production of our raw materials nor are expected to be part of the raw materials used to manufacture of our products. We also do not intentionally use any of these substances in our production process, so we do not expect them to be contained in our products. However, our products have not been tested:

- ✓ 5-tert-butyl-2,4,6-trinitro-m-xylene
- ✓ 4,4'- Diaminodiphenylmethane (MDA)
- ✓ 2-phenyl-3,3-bis(4-hydroxyphenyl)phthalimidine
- ✓ 2,4-Dinitrotoluene
- ✓ 2-chloroacetamide
- ✓ 2-ethylhexyl 10-ethyl-4, 4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)
- ✓ 4-(1,1,3,3-tetramethylbutyl) phenol
- ✓ 2,4-dimethyl-6-tert-butylphenol
- ✓ Reaction mass of DOTE and MOTE
- ✓ 2,4-Pentanedione
- ✓ 1,3-bis(isocyanatomethyl)benzene
- ✓ Acetyl tributyl citrate (ATBC)
- ✓ Adipates
- ✓ Aromatic amines
- ✓ Arsenic
- ✓ Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)
- ✓ Acrylamide
- ✓ Alkylphenol Ethoxylates, including nonylphenol ethoxylate and octylphenol ethoxylate
- ✓ Allergens, such as peanuts, tree nuts, milk, eggs, wheat gluten, soy, fish, and shellfish

- ✓ Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfill the two following conditions:
  - a) Al<sub>2</sub>O<sub>3</sub> and SiO<sub>2</sub> are present within the following concentration ranges:
    - Al<sub>2</sub>O<sub>3</sub>: 43.5 – 47 % w/w, and SiO<sub>2</sub>: 49.5 – 53.5 % w/w, or
    - Al<sub>2</sub>O<sub>3</sub>: 45.5 – 50.5 % w/w, and SiO<sub>2</sub>: 48.5 – 54 % w/w,
  - b) fibres have a length weighted geometric meaning a diameter less two standard geometric errors of 6 or less micrometres (µm). - Extracted from Index no.: 650-017-00-8 - 13.01.2010
- Carcinogenic (article 57a) (support doc.) ED/68/2009
  - ✓ Ammonium dichromate
  - ✓ Anthracene
  - ✓ Anthracene oil, anthracene paste
  - ✓ Antraquinone (9,10-Anthracenedione)
  - ✓ Antimony tris (ethylene glycolate)
  - ✓ Asbestos
  - ✓ Azo compounds
  - ✓ Benzophenone(n) and derivatives
  - ✓ Michler's ketone (4,4-bis(dimethylamino)benzophenone)
  - ✓ DEAB (4,4-bis(diethylamino)benzophenone)
  - ✓ Benzo chrysene
  - ✓ 4-methylbenzophenone
  - ✓ 4-hydroxybenzophenone
  - ✓ ITX, TXIB
  - ✓ Benzyl butyl (BBP)
  - ✓ Beryllium oxide
  - ✓ Beryllium copper
  - ✓ Benzenamine (BNST)
  - ✓ 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)
  - ✓ 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)
  - ✓ Bis(tributyltin)oxide (TBTO)
  - ✓ Bisphenols including:
    - 2,2-Bis(4-hydroxyphenyl)propane - (bisphenol A) ;
    - 2,2-dimethoxy-2-phenylacetophenone
    - 1,1-Bis(4-hydroxyphenyl)-1-phenyl-ethane - (bisphenol AP) ;
    - 2,2-Bis(4-hydroxyphenyl)hexafluoropropane -(bisphenol AF) ;
    - 2,2-Bis(4-hydroxyphenyl)butane - (bisphenol B) ;
    - Bis-(4-hydroxyphenyl)diphenylmethane - (bisphenol BP) ;
    - 2,2-Bis(3-methyl-4-hydroxyphenyl)propane - (bisphenol C) ;
    - Bis(4-hydroxyphenyl)-2,2-dichlorethylene - (bisphenol C) ;
    - bis(2-methoxyethyl) ether
    - 1,1-Bis(4-hydroxyphenyl)ethane - (bisphenol E) ;
    - Bis(4-hydroxydiphenyl)methane - (bisphenol F) ;
    - 2,2-Bis(4-hydroxy-3-isopropyl-phenyl)propane - (bisphenol G) ;
    - 1,3-Bis(2-(4-hydroxyphenyl)-2-propyl)benzene - (bisphenol M) ;
    - Bis(4-hydroxyphenyl)sulfone - (bisphenol S) ;
    - 1,4-Bis(2-(4-hydroxyphenyl)-2-propyl)benzene- (bisphenol P) ;
    - 5,5'-(1-Methylethyliden)-bis[1,1'-(bisphenyl)-2-ol]propane - (bisphenol PH) ;
    - 1,1-Bis(4-hydroxyphenyl)-3,3,5-trimethyl-cyclohexane - (bisphenol TMC) ;
    - 1,1-Bis(4-hydroxyphenyl)-cyclohexane - (bisphenol Z) ;
    - Bis 204-2(2-ethylhexy) phthalate (DEHP) ;
  - ✓ Boric acid

- ✓ Borax
- ✓ Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)
- ✓ Bovine Spongiform Encephalopathy (BSE)
- ✓ 1,3-Butadiene
- ✓ Carbon black and carbon pigments
- ✓ Casein
- ✓ Cellulose and other biopolymers as polynucleotides, polypeptides, and polysaccharides
- ✓ Cobalt dichloride
- ✓ Cadmium
- ✓ Chlorinated aliphatic compounds
- ✓ Chlorine bleach
- ✓ Deca Brominated Diphenyl Ethers (Deca BDE)
- ✓ Dioxan
- ✓ Dioxins and derivatives
- ✓ Diarsenic trioxide
- ✓ Diarsenic pentaoxide
- ✓ Disodium tetraborate, anhydrous
- ✓ Dibutyl phthalate (DBP)
- ✓ Diethyl phthalate (DEP)
- ✓ Di-(2-ethylhexyl) phthalate
- ✓ Di-n-hexyl phthalate (DnHP)
- ✓ Di-n-octyl phthalate (DnOP)
- ✓ Dibutyltin (DBT)
- ✓ Dioctyltin (DOT)
- ✓ Dipropylene Glycol Dibenzoate (DPGDB)
- ✓ Dymethyl fumarate (DMF)
- ✓ Ethylene glycol dimethyl ether (EGDME)
- ✓ Ethylene oxide
- ✓ Epoxy derivatives listed in EU Directive 2002/16/EC
- ✓ Glyoxale (oxaldehyde)
- ✓ Halogens (Fluorine , Chlorine , Bromine , Iodine) and derivatives
- ✓ Hexane (n-hexane, isohexane, neohexane, cyclohexane)
- ✓ Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified
  - Alpha-hexabromocyclododecane,
  - Beta-hexabromocyclododecane,
  - Gamma-hexabromocyclododecane
- ✓ Hazardous Air Pollutants (HAP)
- ✓ Heterocyclic organic compounds
- ✓ Hydrofluorocarbon (HFC), Hydrochlorofluorocarbons (HCFC), Perfluorocarbon (PFC)
- ✓ Sulfur hexafluoride (SF<sub>6</sub>)
- ✓ Lactic acid
- ✓ Lead
- ✓ Lead chromate
- ✓ Lead chromate molybdate sulphate red (C.I. Pigment Red 104)
- ✓ Lead sulfochromate yellow (C.I. Pigment Yellow 34)
- ✓ Lead hydrogen arsenate
- ✓ Formaldehyde
- ✓ Furfural
- ✓ Melamine (1,3,5-Triazine-2,4,6-triamine) and Cyanuric acid (1,3,5-Triazine-2,4,6-triol)
- ✓ Methyl bromide
- ✓ N-Ethyl-o(or p)-toluenesulfonamide
- ✓ Natural rubber latex and dry natural rubber
- ✓ Nitrates and Nitrites

- ✓ Nitrosamine
- ✓ Nonyl phenol
- ✓ Nonyl- and octylphenoles
- ✓ N,N-dimethylacetamide (DMAC)
- ✓ N-Methyl-2-pyrrolidone (NMP)
- ✓ Ozone-depleting substances (ODS)
- ✓ Organic Tins
- ✓ Organo-Tin Compounds
- ✓ Organophosphorus compounds
- ✓ Organic Fluorinated substances
- ✓ o-xylene (xylol)
- ✓ Oxo-degradable additives
- ✓ PAN ( Polyacrylonitrile)
- ✓ Parabens
- ✓ Perchlorates
- ✓ PET (Polyethylene terephthalate)
- ✓ Pesticides, biocides, herbicides, fungicides, preservatives
- ✓ Pitch, coal tar, high temp.
- ✓ Phenol(s)
- ✓ 2-Phenylphenol, 3-Phenylphenol, 4-Phenylphenol
- ✓ Photoinitiators
- ✓ Polyacrylonitrile (PAN) – Acrylonitrile (107-13-1) monomer, Polyacrylonitril
- ✓ Polychlorinated and Polybrominated Biphenyls (PCBs and PBBs)
- ✓ Polychlorinated and Polybrominated Terphenyls (PCTs and PBTs)
- ✓ Polychlorinated naphthalenes (PCN)
- ✓ Polybrominated Diphenyl Ethers (PBDEs)
- ✓ Polychlorinated diphenyl ethers (PCDEs)
- ✓ Polycyclic aromatic hydrocarbons (PAHs)
- ✓ Polyamides
- ✓ Polystyrene (PS)
- ✓ Per- and polyfluoroalkyl substances (PFAS) such as perfluorooctanoic acid (PFOA), perfluorooctane sulfonates (PFOS), (PFHxS), (PFNA), (PFDA), (PFCs) and others.
- ✓ Peroxides and Organic peroxides
- ✓ Polyaromatic Hydrocarbons
- ✓ Potassium chromate
- ✓ Potassium dichromate
- ✓ Quaternary ammonium compounds (including DDAC and BAC)
- ✓ Radioactive Substances
- ✓ Rosin
- ✓ Siloxanes
- ✓ Sodium chromate
- ✓ Sodium antimonite
- ✓ Styrene
- ✓ Sodium dichromate
- ✓ Short-chain chlorinated paraffins(SCCP)
- ✓ Specific azo compounds
- ✓ Sulphur and organosulphur compounds
- ✓ Tetraboron disodium heptaoxide, hydrate
- ✓ Tetrabromobisphenol A (TBBPA)
- ✓ Toluene
- ✓ Triclosan
- ✓ Trichloroethylene
- ✓ Triethyl arsenate

- ✓ Triphenyltin (TPT)
- ✓ Tris-Nonylphenol Phosphite
- ✓ Tris(2-chloroethyl)phosphate
- ✓ Trixylyl phosphate (TXP)
- ✓ Transmissible Spongiform Encephalopathy (TSE)
- ✓ Urea-formaldehyde resins or polymers
- ✓ Vinyl Chloride Monomer (VCM), Polyvinyl Chloride (PVC), Polyvinylidencchlorid (PVdC)
- ✓ Volatile Organic Compounds (VOC)
- ✓ Zirconia Aluminosilicate Refractory Ceramic Fibres

are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions:

a) Al<sub>2</sub>O<sub>3</sub>, SiO<sub>2</sub> and ZrO<sub>2</sub> are present within the following concentration ranges:

- Al<sub>2</sub>O<sub>3</sub>: 35 – 36 % w/w, and
- SiO<sub>2</sub>: 47.5 – 50 % w/w, and
- ZrO<sub>2</sub>: 15 - 17 % w/w,

- ✓ b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm).
- ✓ POSH (polyolefin oligomeric saturated hydrocarbons)
- ✓ MOSH (Mineral Oil Saturated Hydrocarbon), MOAH (Mineral Oil Aromatic Hydrocarbon)
- ✓ Isopropylthioxanthone (ITX)
- ✓ Titan-Acetylaceton (TAA)
- ✓ Fluoro-Surfactants, reference substance PFOS
- ✓ PFOA
- ✓ Azodicarbonamide, semicarbazide
- ✓ Ethylhexanoic acid
- ✓ PAA (Primary Aromatic Amines)
- ✓ Soy Bean oil epoxide (ESBO)
- ✓ Pigments based on Antimony, Arsenic, Cadmium, Chrome IV, Plumb,
- ✓ Quicksilver
- ✓ Chlorobenzene, Dichlorobenzene
- ✓ Nitropropane
- ✓ CHC (Chlorinated hydrocarbons),
- ✓ CFC (chlorofluoro-carbons)
- ✓ Chlorinated paraffines and PAHs
- ✓ Hexachlorocyclohexane
- ✓ Di-Amino-Stilbene
- ✓ Nitrosamine
- ✓ Perbromated flame retardants
- ✓ Benzol (Benzene), Furan
- ✓ Pentachlorophenol (PCP)
- ✓ Polychlorinated Bi- and Terphenyles (PCB, PCT)
- ✓ Polychlorinated dibenzodioxins (PCDDs) and- furanes (PCDF)

### 11. Kosher certified

Plastchim-T AD is a plastic film manufacturing facility that has no type of foods or food type materials involved within the processes or operations. To be Certified by a Rabbi of the Jewish Faith is not considered applicable for this type of facility

### 12. Halal statement

We can say that among the large variety of polymer additives that we are using in our BOPP films, only a few of them may be formulated with substances of animal origin. Our suppliers claim

that the processing of such animal derived substances is made under rigorous conditions, considered unlikely to be infectious irrespective of geographical origin and the nature of the tissues from which they are derived. Our suppliers also claimed that the raw materials that they use and the finished products they sell comply with the existing legislations. Concerning the absence of wine, ethyl alcohol or spirits in all BOPP films, we can say that they are not formulated with this substance, which means that we do not intentionally use it as raw material. Therefore, we do not expect its presence. This concerns only the composition of BOPP films produced by us and does not guarantee the compliance of final articles made by using our BOPP films.

### 13. Recyclability

All types of BOPP films of PLASTCHIM-T AD are 100% recyclable as per industry standards and procedures according CEN Standard EN 13430:2004



CEN Standard EN 13432:2004 - this product is not suitable for composting.

Energy Recovery - CEN Standard EN 13431:2004 – the calorific gain from polypropylene in an energy recovery process is 24 MJ/kg.

### 14. Changes

If any significant changes that can cause changes in the migration are made in the production process, this declaration will be changed accordingly. We declare also that during processing of the goods nothing will be changed without announcement to the customer.

**This document is valid from the date of issue until the next edition**

**Edition 16 / Last updated on 19 January 2023**

#### **Disclaimer:**

**This declaration has been prepared and issued on the basis of information provided by our raw material suppliers, of currently applicable laws and regulations, and to the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication. PLASTCHIM-T AD makes no warranties which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose. It is the customer's responsibility to inspect and test our products in order to satisfy itself as to the suitability of the products for the customer's particular purpose. The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.**

**No liability can be accepted in respect of the use of PLASTCHIM-T AD products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials.**