



Declaration of Compliance

1. Product Manufacturer - Plastchim-T AD

Seat: Bulgaria, Tervel 9450, Khan Asparuh str., No 97

Production: Bulgaria, Tervel 9450, Khan Asparuh str., No 97

tel.: +359 (0) 52 76 58 61 , fax: +359 (0) 58 690 300

Production of: Flexible packages - FIBC (big bags), sewn small bags and PP block bottom bags, PP sleeve (circular) fabric (coated and uncoated), PP twine.

2. Used materials for production of flexible packaging:

- PP homopolymer (types mostly used: PP F401, PP F400 BO, PP J1000, Buplen 6631, Ecolen HSP и Y 1000)

- PE (types mostly used: LDPE B20/0.3, Ineos 23H430)

- Additives to achieve physical and mechanical characteristics of packages (types mostly used: CS275LL, CSW160, PE4884, FX1080 LL SV, Granic 1025, Arguvin 258 PP).

All used materials are suitable for food contact and there is no presence of functional barrier.

3. This declaration is issued on 19. 01. 2023

We declare and confirm that all types of Flexible packages, produced from Plastchim-T AD meet the requirements listed in:

- Regulations №1245/2020, №2019/1338, №2019/37, №2018/831, №2018/213; № 79/2018, № 202/2014, №174/2015, № 2016/1416 and № 2017/752 amending Regulation 10/2011/EC, having regard to Regulation (EC) No 1935/2004 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(1) amended by Commission Regulation (EC) No. 450/2009.

- 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,

- 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 declare that is in compliance with general rules on good manufacturing practice (GMP).

4. During the production of Flexible packages we do not intentionally add substances, that exceed SM limits according Regulation № 10/2011/EC (Annex I, Annex II Substances) with amendments as follows: Regulation (EC) №2019/1338, Regulation (EC) №2019/37, Regulation (EC) №2018/831, Regulation (EC) №2018/213; Regulation (EC) № 2018/79, Regulation (EC) № 2017/752, Regulation (EC) №2016/1416, Regulation (EC) №2015/174, Regulation (EC) №202/2014, Regulation (EC) №1183/2012, Regulation (EC) №1282/2011 and Regulation (EC) №321/2011.

- 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.

- According to the information received by our suppliers the additives and PP Homopolymers and PE, used for the production of Flexible packages do not contain any genetically modified organisms (GMO), palm oil, NANO materials and Animal Derived Materials. Plastchim-T AD can state also that we do not intentionally use or add genetically modified organisms (GMO), palm oil, NANO materials and Animal Derived Materials.

- According to the information received from our suppliers the additives and PP Homopolymers and PE Plastchim-T AD can state that according Regulation № 1907/2006/EC 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 Flexible packages.

- None of the following substances are used in the process nor are they expected to be part of the raw materials to manufacture this product:

- ✓ 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
- ✓ Reaction mass of DOTE and MOTE
- ✓ 2,4-Pentanedione
- ✓ 1,3-bis(isocyanatomethyl)benzene
- ✓ Adipates
- ✓ Aromatic amines
- ✓ Arsenic
- ✓ Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)
- ✓ Acrylamide
- ✓ Alkylphenol Ethoxylates, including nonylphenol ethoxylate and octylphenol ethoxylate
- ✓ Ammonium dichromate
- ✓ Anthracene
- ✓ Anthracene oil, anthracene paste
- ✓ Asbestos
- ✓ Azo compounds
- ✓ 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)
- ✓ Casein
- ✓ Cobalt dichloride
- ✓ Cadmium
- ✓ Chlorine bleach
- ✓ Dioxins
- ✓ 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)
- ✓ Dymethyl fumarate (DMF)
- ✓ Ethylene glycol dimethyl ether (EGDME)
- ✓ Epoxy derivatives listed in EU Directive 2002/16/EC
- ✓ Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified
Alpha-hexabromocyclododecane,
Beta-hexabromocyclododecane,
Gamma-hexabromocyclododecane
- ✓ Hazardous Air Pollutants (HAP)
- ✓ Hydrofluorocarbon (HFC), Hydrochlorofluorocarbons (HCFC), Perfluorocarbon (PFC)
- ✓ Sulfur hexafluoride (SF₆)
- ✓ 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
- ✓ Methyl bromide
- ✓ Natural rubber latex and dry natural rubber
- ✓ Nitrosamine
- ✓ Nonyl phenol
- ✓ Nonyl- and octylphenoles
- ✓ N,N-dimethylacetamide (DMAC)
- ✓ Ozone-depleting substances (ODS)
- ✓ Organic Tins
- ✓ PAN (Polyacrylonitrile)
- ✓ Parabens
- ✓ Perchlorates
- ✓ PET (Polyethylene terephthalate)
- ✓ Pitch, coal tar, high temp.
- ✓ Phenol
- ✓ Polyacrylonitrile (PAN) – Acrylonitrile (107-13-1) monomer, Polyacrylonitril
- ✓ Polychlorinated and Polybrominated Biphenyls (PCBs and PBBs)
- ✓ Polychlorinated and Polybrominated Terphenyls (PCTs and PBTs)
- ✓ Polychlorinated naphtalenes (PCN)
- ✓ Polybrominated Diphenyl Ethers (PBDEs)
- ✓ Polycyclic aromatic hydrocarbons (PAHs)
- ✓ Polystyrene (PS)
- ✓ Perfluorooctanoic Acid (PFOA), Perfluorooctane Sulfonates (PFOS) , (PFHxS), (PFNA), (PFDA), (PFCs)
- ✓ Polyaromatic Hydrocarbons
- ✓ Potassium chromate
- ✓ Potassium dichromate
- ✓ Radioactive Substances
- ✓ Rosin
- ✓ Siloxanes
- ✓ Sodium chromate
- ✓ Styrene
- ✓ Sodium dichromate
- ✓ Short-chain chlorinated paraffins(SCCP)
- ✓ Specific azo compounds
- ✓ Organo-Tin Compounds
- ✓ Organic Fluorinated substances
- ✓ Tetraboron disodium heptaoxide, hydrate
- ✓ Tetrabrombisphenol A (TBBPA)
- ✓ Toluene
- ✓ Triclosan
- ✓ Trichloroethylene
- ✓ Triethyl arsenate
- ✓ Triphenyltin (TPT)
- ✓ Tris-Nonylphenol Phosphite
- ✓ Tris(2-chloroethyl)phosphate

- ✓ Trixylyl phosphate (TXP)
- ✓ Transmissible Spongiform Encephalopathy (TSE)
- ✓ Vinyl Chloride Monomer (VCM), Polyvinyl Chloride (PVC), Polyvinylidenchlorid (PVdC)
- ✓ Volatile Organic Compounds (VOC)
- ✓ MOSH(Mineral Oil Saturated Hydrocarbon) , MOAH(Mineral Oil Aromatic Hydrocarbon)
- ✓ Isopropylthioxanthone (ITX)
- ✓ Titan-Acetylacetone (TAA)
- ✓ Fluro-Surfactants, reference substa PFOS
- ✓ PFOA
- ✓ Azodicarbonamide
- ✓ Ethylhexanoic acid
- ✓ PAA (Primary Aromatic Amins)
- ✓ Soy Bean oil epoxide (ESBO)
- ✓ Pigments based on Antimony, Arsenic, Cadmium, Chrome IV, Plumb,
- ✓ Quicksilver
- ✓ Chlorobenzen, Dichlorobenzen
- ✓ Nitropropane
- ✓ CHC (Chlorinated hydrocarbons),
- ✓ CFC (chlorofluoro-carbons)
- ✓ Chlorinated paraffines and PAHs
- ✓ Hexachlorocyclohexane
- ✓ Di-Amino-Stilbene
- ✓ Nitrosamine
- ✓ Perbromated flame retardants
- ✓ Benzol, Furan
- ✓ Pentachlorophenol (PCP)
- ✓ Polychlorinated Bi-and Terphenyles (PCB, PCT)
- ✓ Polychlorinated dibenzodioxins (PCDDs) and- furanes (PCDF)

- No allergens, such as peanuts, tree nuts, milk, eggs, wheat gluten, soy, fish, and shellfish

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

- 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 would violate governmental guidelines.

Regulation (EC) No 1907/2006 – REACH of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency.

Plastchim-T AD does not need to register or pre-register its own Flexible packages. Under the EC Regulation REACH this products are classified as a preparation. Our suppliers confirm that all substances of this preparation are compliant with 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 also that we don't intentionally use or add any substances of very high concern (SVHC) published on the latest version of REACH Candidate list published on 17 January 2023 on the ECHA website: <https://echa.europa.eu/bg/candidate-list-table/>

This products therefore meets the relevant requirements of the following Directives or Regulations:

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.

Regarding Directive 89/107/EC Annex 1. We don't use following food additives: Colour, Preservative, Anti-oxidant, Emulsifier, Emulsifying salt, Thickener, Gelling agent, Stabilizer, Flavour enhancer, Acid, Acidity regulator, Anti-caking agent, Modified starch, Sweetener, Raising agent, Anti-foaming agent, Glazing agent, Flour treatment agent, Firming agent, Humectant, Sequestrant, Enzyme, Bulking agent, Propellant gas and Packaging gas.

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.

Stockholm Convention – Regarding Regulation (EC) No 850/2004 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.

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 products.

Based on the available documentation from raw materials suppliers, this product complies with the requirements of the Directives 2002/95/EC and 2011/65/EU, as amended (RoHS), 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).

5. Dual-use additives

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

Table 2

FCM substance №	Ref №	CAS №	Substance name	SML	Max. content (calculated)
-	-	471-34-1	Calcium carbonate CaCO ₃ (E170)	-	5%
411	42080	1333-86-4	Carbon black (E153)	-	0.05%
610	93440	13463-67-7	Titanium Dioxide TiO ₂ (E171)	-	0.2%

We declare also that none of the ingredients used during the production of the aforementioned products contain substances that exceed the limits of Regulation 10/2011/EC.

For more detailed information please contact with sales department representative.

6. 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.

7. Specifications on the use of Flexible packages:

- Products suitable for storage and transport in flexible packages - construction materials, fertilizers, minerals, chemical products, feed and agricultural products, paper and plastic waste, food products and others.

- Flexible packages is tested for contact with dry foods regarding Methods described in Annex III in [Regulation 10/2011/EC](#) (Table 1, List of food simulants).

- Proper use and storage:

Do not exceed the declared capacity;

Fill the evenly;

During the filling, take care of static electricity;

Do not slide packages on the floor;

Do not store in the sun for a long time;
 Be stored at 0° C to 40° C;
 Keep away from sources of heat or fire without UV radiation.

8. 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: PAA, melamine, Formaldehyde and hexamethylenetetramine, 4-metyl-1-penten and metals.

A representative sample of these flexible packages 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 E at the condition of 10 days at 60°C.

Table 1

Nº	Name of the index	Units	Measured value	Tolerance	Test conditions
1.	Overall migration	mg/dm ²	< 1.1	10	10 days 60 °C with MPPO (Food simulant E)
2.	Specific migration – formaldehyde and hexamethylenetetramine	mg/kg	HCHO < 0.05 HMTA < 0.07	15	10 days 60 °C with MPPO (Food simulant E)
3.	Specific migration - metals	mg/kg	Al < 0.2 Ba < 0.1 Co < 0.03 Cu < 0.2 Fe < 0.2 Li < 0.05 Mn < 0.1 Zn < 0.2	Al – 1 Ba - 1 Co - 0.05 Cu – 5 Fe - 48 Li – 0.6 Mn – 0.6 Zn – 5	10 days 60 °C with MPPO (Food simulant E)
4.	Specific migration - 4-metyl-1-penten	mg/kg	<0.009	<0.05	10 days 60 °C with MPPO (Food simulant E)
5.	Specific migration 2,4,6 – triamino – 1,3,5 – triazine (melamine)	mg/kg	<0.9	<0.15	10 days 60 °C with MPPO (Food simulant E)
6.	Specific migration - primary aromatic amines	mg/kg	<0.01	<0.01	10 days 60 °C with MPPO (Food simulant E)

9. Recyclability

All types of Flexible packages of PLASTCHIM-T AD are recyclable as per industry standards and procedures



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

Energy Recovery - CEN Standard EN 13431:2004 – the calorific gain from polyethylene in an energy recovery process is 22 MJ/kg

10. If any significant changes will be made in the production process, which can cause changes in the migration, this declaration will be changed accordingly.

Edition 4 / Last updated on 19. 01. 2023

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

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.