

DECLARATION OF COMPLIANCE FOR FOOD CONTACT

This document is a declaration of compliance with the European Union regulations for food contact plastics and contains information required by Commission Regulation (EU) 10/2011 and subsequent amendments up to (EU) 2019/37 and EU guidance issued on 21.02/2014.

The statement also includes reference to compliance with Switzerland and FDA regulations.

This column identifies the clause in EU Guidance for DoC.

MANUFACTURER OF PLASTIC INTERMEDIATE MATERIAL

Alpek Polyester UK Ltd.
 Davies Offices
 Wilton Site
 Redcar
 TS10 4XZ United Kingdom

EU DoC ref. 1 & 2

PRODUCTS

Polyethylene Terephthalate Resin CAS (25038-59-9)

Trademarks:



EU DoC ref. 3

EUROPEAN FOOD CONTACT

APUK Ltd confirm that PAPET Max™, PAPET Clear™ and PAPET Pure™ resins comply with the relevant requirements of the Framework Regulation EC 1935/2004 for materials to come into contact with foodstuffs and with the Regulation EU 10/2011 plastic materials and articles intended to come into contact with food and its amendments as a Plastic Intermediate Material. These resins are made to good manufacturing practice (GMP) standards compliant with EU regulation (EC) 2023/2006. Only those monomers listed in the Union List Regulation are used to manufacture APUK resins.

Intentionally added substances (IAS) not subject to listing in the Union List comply with the relevant requirements of the Framework Regulation and a risk assessment in accordance with Article 19 of the Plastics Regulation has been performed. IAS include colour modification agents; these are listed in the French authorities positive list, Circulaire No 176 of 2 December 1959 relating to pigments and colorants in plastic materials and packaging, and meet the Council of Europe AP(89)1 purity criteria. These approved pigments do not migrate in detectable concentrations.

A generic risk assessment based on existing scientific data and on established end-uses has been carried out and there is currently no evidence that PET contains Non-Intentionally Added Substances (NIAS) that would be of concern. The Committee of PET Manufacturers in Europe (CPME) has commissioned extensive analysis of the reaction intermediates, decomposition or reaction products commonly referred to as (NIAS) of all PET plastics intermediate material

EU DoC ref. 5a

EU DoC ref. 5b, 6a & 6b

EU DoC ref. 5c

EUROPEAN FOOD CONTACT cont'd

manufactured by its members including PET manufactured by APUK. The analysis confirms that NIAS comply with the relevant requirements of the Framework Regulation and that a risk assessment in accordance with Article 19 of the Plastics Regulation has been performed. The CPME NIAS analysis and risk assessment processes are retained by CPME for inspection by a Competent Authority as Supporting Documentation. Information on how to carry out a PET NIAS analysis and risk assessment can be obtained by contacting CPME at info@CPME.org.

Substances that have Specific Migration Limits (SMLs) or restrictions are listed below:

| Substance | Regulation Reference | Restriction / SML |
|--------------------------------------|--------------------------------|----------------------|
| Terephthalic acid | PM/Ref. 24910 | SML 7.5 mg/kg |
| Isophthalic acid | PM/Ref. 19150 | SML 5 mg/kg |
| Ethylene glycol Diethylene glycol | PM/Ref. 16990 PM/Ref. 15760 | SML 30mg/kg (total) |
| Antimony based catalyst | PM/Ref. 35760 | SML 0.04 mg/kg |
| Titanium Nitride | PM/Ref. 93485 | Addition rate <20ppm |

APUK resins do not intentionally contain substances listed in point 1 of Annex II of the Plastics Regulation or release Primary Aromatic Amines.

APUK declares that Phosphoric Acid which is also a food additive E338 is regarded as a dual use additive that complies with purity limits 2008/84/EC.

With respect to some specific national legislation, APUK confirms that the composition of the polymer does not contravene the following for food packaging materials:

- The German Bfr Recommendation XVII Poly(terephthalic acid diol esters)
- Dutch warenwet Regeling Verpakkingen en gebruiksartikelen Bijlage Deel A Hoofdstuk I lijst 2
- (Dutch commodities Act Regulation on packaging and consumer items Annex part A chapter I list 2)

Fabricated test materials have been tested in accordance with EU Directives for food contact with all aqueous and fatty foods. The results demonstrate that the polymer meets the migration limits as above when tested for 10 days at 40°C or 60°C in simulants specified by the Regulation (EU) 10/2011 using test methods EN1186-1,2 and 3 and a ratio of 2dm²/100mL and simulants 20%, 50% ethanol, 3% acetic acid and olive oil. Testing on fabricated materials has also demonstrated that the material complies with the specific migration levels when using 50% alcoholic simulants.

DOWNSTREAM USER RESPONSIBILITIES

The Plastics Regulation EU 10/2011 specifies certain responsibilities across the entire supply chain for food contact materials and articles. As a plastic intermediate manufacturer, APUK can ensure its products in typical PET resin applications comply but it cannot confirm all downstream applications will be suitable. When processed from a plastic intermediate material into the final article, PET resin is often modified with colour agents, recyclate or other substances and usually subjected to thermal transformation that can generate NIAS or affect migration. Therefore, in order to comply with EU 10/2011 it is the responsibility of the downstream user to conduct appropriate risk assessments, which may include migration and NIAS analysis to assess the effect of any downstream processing on the final food contact article.

NON-EUROPEAN FOOD CONTACT

USA FDA Code:

The polymer grades PAPET Clear, PAPET Max, PAPET Pure comply with the compositional requirements of FDA regulation for material in contact with food 21 CFR 177.1630 – Polyethylene Phthalate polymers.

Although not being a member state, Switzerland has signed some contracts of Greater Europe. The Swiss Food Contact (FC) CH LGV 817.02 regulation has adapted most of European FC regulation. The Swiss regulatory authorities state that they accept material which is accepted by the European Union.

GENERAL

APUK is ISO 9001 and ISO 14001 registered.

APUK confirms that there is no intentional addition of the following during the manufacture of PAPET Resins:

- Bisphenol A during in respect of EU 321/2011;
- Plasticisers;
- Epoxy derivatives;
- PVC;
- Polycyclic Aromatic Hydrocarbons;
- Any substances listed on the most recent Candidate list for SVHC;
- Cadmium, mercury, lead or chromium, or their compounds.

PAPET Clear™, PAPET Max™, PAPET Pure™ content in final articles will not prevent the articles from complying with the EU Packaging & Packaging Waste Directive (94/62/EC) and its amendment 2004/12/EC.

As defined in the REACH regulations PAPET Max™, PAPET Clear™ and PAPET Pure™ are all polymers and therefore do not need to be registered. APUK confirm that raw materials suppliers have declared that their substances used by APUK are REACH registered where required.

APPROVAL

Approved by:



J R Baker
Senior Technologist

This information is believed to be accurate and given in good faith, but you must satisfy yourself as to its suitability (and that of the product) for your purposes, for environmental protection and for the safety of your employees/contractors and customers. No warranty as to the fitness of the product for your (or any other) purposes is given or can be implied.