

DECLARATION of COMPLIANCE

for products made of PET (polyethylene terephthalate) intended to come into contact with food

PET Bottle Grade K-080

KÖKSAN PET

COMPLIANCE WITH EU REGULATIONS FOR FOOD CONTACT PLASTICS

Köksan PET Polyester Resin K-080 is produced by using only the monomers and additives listed in below given EU Directives. We herewith confirm that our product which is KÖKSAN PET RESIN K-080 is in compliance with the requirements of the following regulations:

- Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and its 5 amendments : Commission Regulation (EU) No 202/2014, Commission Implementing Regulation (EU) No 321/2011, Commission Regulation (EU) No 1183/2012, Commission Regulation (EU) No 1282/2011 and Commission Regulation (EU) 2015/174.
- Regulation 1935/2004/EC on materials and articles intended to come into contact with food.
- Commission Regulation (EC) NO 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.
- Commission Directive 94/62/EC on packaging and packaging waste and its 3 amendments : Directive 2004/12/EC, Directive 2005/20/EC and Directive 2013/2/EU.

Compliance with the migrational requirements of the above mentioned Commission Directives is demonstrated by tests carried out on our Preform products.

Overall and specific migrations of substances were determined by using food simulants and pre-defined conditions(time and temperature). The migration results do not exceed the limits set out in directive (EC) No 10/2011. The test conditions(Table1) and results(Table2) are as follows:

Test	Simulant	Test Conditions
Heavy Metals (Pb,Cd,Hg,Cr(VI)) (EU Packaging Directive 94/62/EC)		
Overall Migration	20% ethanol	10d, 40°C
Specific Migration of Heavy Metals (Ba,Co,Cu,Fe,Li,Mn,Zn)	20% ethanol	10d, 60°C

KÖKSAN PET ve PLASTİK AMBALAJ
SAN. TİC. A.Ş.

4. OSB 82414 nolu cad.
No:16 27600 Şehitkamil
Gaziantep / TÜRKİYE
Tel: 90 342 357 03 30(pbx)
Fax: 90 342 357 03 39
www.koksan.com



Specific Migration of terephthalic acid and isophthalic acid	20% ethanol & 3% acetic acid	10d, 60°C
Specific Migration of ethylene glycol and diethylene glycol	20% ethanol & water	10d, 60°C
Specific Migration of Antimony	20% ethanol & 3% acetic acid	10d, 60°C

Table 1 – Test Conditions

Substance	Migration	Limit	Results
	Overall	<60 mg/kg	n.d.
Terephthalic acid	specific	<7,5 mg/kg	<0,5 (3% acetic acid)
Terephthalic acid	specific	<7,5 mg/kg	<0,5 (20% ethanol)
Isophthalic acid	specific	<5 mg/kg	<0,5 (3% acetic acid)
Isophthalic acid	specific	<5 mg/kg	<0,5 (20% ethanol)
MEG + DEG	specific	<30 mg/kg	
MEG	specific		<10 (%20 ethanol)
MEG	specific		<10 (water)
DEG	specific		<10 (%20 ethanol)
DEG	specific		<10 (water)
Antimony	specific	max. 0,04 mg/kg	0,04 (3% acetic acid)
Antimony	specific	max. 0,04 mg/kg	0,03 (20% ethanol)

n.d. : not detected

Table 2 – Test Results

The limit of total heavy metals [Pb+Cd+Hg+Cr(IV)] is 100 mg/kg and 5 mg/kg individually according to the Directive 94/62/EC. The migration values were determined as n.d. individually and totally.

Specific migration result of heavy metals (Ba,Co,Cu,Fe,Li,Mn,Zn) were also determined as n.d. individually with reference to Commission Regulation (EU) No 10/2011.

Please, be informed that as our downstream user, the overall and specific migration results obtained were below the migration limits defined in EC Directive.

We confirm that our products KÖKSAN PET Resin K-080 fully complies with the European Commission Regulation (EU) 10/2011 for Plastic-Overall Migration and Specific Migration for Heavy Metals as per tests made by SGS, Test Report No. TR563560 R1.

KÖKSAN PET

COMPLIANCE WITH FDA REGULATIONS FOR FOOD CONTACT PLASTICS

KÖKSAN PET Polyester Resins are in compliance with the FDA Code of Federal Regulations CFR21 Section 177.1630(Polyethylene Phthalate Polymers).

Compliance with the migrational requirements of the above mentioned Commission Directive is demonstrated by tests carried out on our preform products.

Please, be informed that as our downstream user, the overall and specific migration results obtained were below the migration limits defined in FDA Regulation.

We confirm that our product KÖKSAN PET Resins fully complies with the USA FDA Code of Federal Regulations CFR21 Section 177.1630.

3 KÖKSAN PET SVHC

We confirm that our products KÖKSAN PET Resins don't contain any of the 168 substances listed on the Candidate List of Substances of Very High Concern (SVHC) which was last updated on the ECHA website on December 17th, 2015, in concentrations equal or higher than 0,1% by weight.

We also confirm that our PET Resins do not contain any of the 22 SVHC in Annex IV of the Commission Regulation (EU) No. 348/2013 published on April 17th, 2013, in concentrations equal or higher than 0,1% by weight.

None of the above mentioned substances, to our knowledge, is generated during the production of PET Resin. It is the responsibility of our downstream users to keep their processes safe and proper.

4 KÖKSAN PET REACH

Polymers are exempted from the REACH registration requirements. However, REACH requires the registration of the raw materials and additives as given below :

- Monomers and the other substances used in the production of the polymer must be registered if the polymer is produced in or imported into the EU contains 2% or more by weight of such monomers and other substances and if the volume of those in reacted form exceeds one metric ton per annum.
- Polymer additives must be registered if they are produced or imported on their own or in compounded form in volumes of one or more metric ton per annum.

Considering the above regulation, the additives we use in the polymer production don't need to be REACH registered. The REACH registration is necessary for the raw materials, PTA, MEG and IPA.

Please, be informed that as our downstream user, we only use the raw materials having the REACH registration provided by the supplier.

We confirm that our products KÖKSAN PET Resins are fully compliant with REACH Regulation (EC) No. 1907/2006.

5 KÖKSAN PET BPA (Bisphenol A)

Bisphenol A (CAS No. 80-05-7) is a monomer of polycarbonate(PC) resin. Polycarbonate is used in the manufacture of food containers, like returnable beverage bottles, infant feeding(baby) bottles, tablewares like plates and mugs, and protective coatings and linings for food and beverage cans. The amendment of the Regulation (EU) N0 10/2011 which is the Commission Implementing Regulation (EU) No 321/2011 says that Bisphenol A is restricted in plastic infant feeding bottles.

We hereby confirm that Bisphenol A is not used as a raw material or an additive during manufacture of our final product *PET Bottle Grade K-080*.

Therefore our product *PET Bottle Grade K-080* is in compliance with the European Commission Regulation (EU) No 321/2011 of 1 April 2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles.

KÖKSAN PET

Phthalates

We hereby declare that no phthalates of whichever chemical form are added to PET Resin of all types produced in KÖKSAN A.Ş.

KÖKSAN PET

Dual Use Additives

We confirm that our PET Resins do not contain any substance defined as 'dual use additive' which is authorized as additive in plastics and at the same time as food additive or flavouring.

KÖKSAN PET

CMR(carcinogens, mutagens or toxic to reproduction) Substances

Mostly 3 different antimony compounds *antimony trioxide*, *antimony triacetate* and *antimony triglycolate*, are used as catalyst in the PET Resin production. These antimony compounds stay in the PET Resin as antimony metal form after the production despite the antimony trioxide is in Table 3.1 (list of harmonised classification and labelling of hazardous substances) which is in the Annex VI of Regulation(EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. In conclusion, we confirm that KÖKSAN PET Resin does not contain antimony trioxide and other CMR substances listed in the Regulation(EC) No 1272/2008.

KÖKSAN PET

EU Pharmacopoeia 6.3 Chapter 3.1.15 "*Polyethylene terephthalate for containers for preparations not for parenteral use*"

KÖKSAN PET RESIN comply with the requirements established by the European Pharmacopoeia in the chapter 3.1.15, requirements mandatory for PolyEthylene Terephthalate containers for preparations not for parenteral use.

This declaration is supported with the analytical tests carried out by the SGS Germany, Report No : TR613747 R1.

The tests and results are in Table 3 below :

Test/Parameter	Method	Specification	Results	Status
Identification A(UV-vis)	EP(2.2.25)		meets spec.	Pass
Identification B (IR)	EP(2.2.24)		meets spec.	Pass
Appearance of soln. S1	EP(2.2.1)		meets spec.	Pass
Appearance of soln. S2	EP(2.2.1&2.2.2,II)		meets spec.	Pass

Alkalinity	EP	max. 0,5ml	0,102ml	Pass
Acidity	EP	max. 0,5ml	0,130ml	Pass

Table3 – Tests and results of EU Pharmacopoeia 6.3, Ch. 3.1.15

Test/Parameter	Method	Specification	Results	Status
Absorbance of soln. S1	EP(2.2.25)	max. 0,20	0,0044	Pass
Absorbance of soln. S2	EP(2.2.25)	max. 0,05	0,0062	Pass
Reducing Substances	EP	0,5ml	0,255ml	Pass
Subs. soluble in Dioxan	EP	max. 3%	0,03 %	Pass
Extractable Aluminium	EP(2.2.57)	max. 1ppm	0,0ppm	Pass
Extractable Antimony	EP(2.2.57)	max. 1ppm	<0,027ppm	Pass
Extractable Barium	EP(2.2.57)	max. 1ppm	<0,002ppm	Pass
Extractable Cobalt	EP(2.2.57)	max. 1ppm	<0,003ppm	Pass
Extractable Germanium	EP(2.2.57)	max. 1ppm	<0,024ppm	Pass
Extractable Manganese	EP(2.2.57)	max. 1ppm	<0,002ppm	Pass
Extractable Titanium	EP(2.2.57)	max. 1ppm	<0,002ppm	Pass
Extractable Zinc	EP(2.2.57)	max. 1ppm	<0,004ppm	Pass
Sulfated Ash	EP(2.4.14)	max. 0,5%	0,0%	Pass

Table3 - Tests and results of EU Pharmacopoeia 6.3, Ch. 3.1.15 (continue)

