

# DECLARATION of COMPLIANCE

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

Certificate Date : 23.02.2016

## PET Bottle Grade K-084 enSave

### 1 COMPLIANCE with EU REGULATIONS FOR FOOD CONTACT PLASTICS

We herewith confirm that our product which is KÖKSAN PET RESIN K-084 enSave 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.
- Türk Gıda Kodeksi gıda ile temas eden plastik madde ve malzemeler tebliği, tebliğ no: 2013/34

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 and results (Table1) are as follows:



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We confirm that our products KÖKSAN PET Resin 'K-084 enSave' 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. TR860245 R1.

### 2 COMPLIANCE with FDA REGULATIONS FOR FOOD CONTACT PLASTICS

We confirm that our product KÖKSAN PET Resins fully complies with the USA FDA Code of Federal Regulations CFR21 Section 177.1630. Compliance with the migrational requirements of the above mentioned Commission Directive is demonstrated by tests carried out on our preform products.

Substance	Migration	Condition	Limit	Result
Pb, Cd, Hg, Cr(IV)			100 mg/kg in total	n.d. individually
Overall Migration	Overall (50% Ethanol)	10d, 40°C	<10 mg/dm <sup>2</sup>	n.d.
Overall Migration	Overall (3% Acetic Acid)	10d, 40°C	<10 mg/dm <sup>2</sup>	n.d.
Ba, Co, Cu, Fe, Li, Mn, Zn	Specific (50% Ethanol)	10d, 60°C		n.d. individually
Ba, Co, Cu, Fe, Li, Mn, Zn	Specific (3% Acetic Acid)	10d, 60°C		n.d. individually
Terephthalic Acid	Specific (50% Ethanol)	10d, 60°C	<7,5 mg/kg	<0,5 mg/kg
Terephthalic Acid	Specific (3% Acetic Acid)	10d, 60°C	<7,5 mg/kg	<0,5 mg/kg
Isophthalic Acid	Specific (50% Ethanol)	10d, 60°C	max. 15 mg/kg	<0,5 mg/kg
Isophthalic Acid	Specific (3% Acetic Acid)	10d, 60°C	max. 15 mg/kg	<0,5 mg/kg
Ethylene Glycol (EG)	Specific (50% Ethanol)	10d, 60°C	max. 30mg(EG+DEG)/kg	<10 mg/kg
Ethylene Glycol (EG)	Specific (3% Acetic Acid)	10d, 60°C	max. 30mg(EG+DEG)/kg	<10 mg/kg
Diethylene Glycol (DEG)	Specific (50% Ethanol)	10d, 60°C	max. 30mg(EG+DEG)/kg	<10 mg/kg
Diethylene Glycol (DEG)	Specific (3% Acetic Acid)	10d, 60°C	max. 30mg(EG+DEG)/kg	<10 mg/kg
Acetaldehyde	Specific (Water)	10d, 60°C	max. 6 mg/kg	<0,01 mg/kg
Antimony	Specific (50% Ethanol)	10d, 60°C	max. 0,04 mg/kg	0,02 mg/kg
Antimony	Specific (3% Acetic Acid)	10d, 60°C	max. 0,04 mg/kg	<0,02 mg/kg
Chloroform-soluble extractives	Distilled Water	24hr, 120°F	0,5 mg/inch <sup>2</sup>	<0,1 mg/inch <sup>2</sup>
Chloroform-soluble extractives	n-Heptane	24hr, 120°F	0,5 mg/inch <sup>2</sup>	<0,1 mg/inch <sup>2</sup>
Chloroform-soluble extractives	8% Alcohol	24hr, 120°F	0,5 mg/inch <sup>2</sup>	<0,1 mg/inch <sup>2</sup>

Table 1 – Test Conditions and Results

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### 3 SVHC COMPLIANCE

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 REACH COMPLIANCE

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 BPA (Bisphenol A) and BPS (Bisphenol S) COMPLIANCE

Bisphenol A is used in the manufacture of polycarbonate(PC) resin as monomer. To comply with restrictions and regulations on BPA due to its confirmed toxicity, manufacturers are gradually replacing BPA with other related compounds, mainly bisphenol S.

We hereby declare that Bisphenol A (CAS No. 80-05-7) and Bisphenol S (CAS No. 80-09-1) are not used as additive or raw material in any stage of KÖKSAN PET Resin manufacturing process.

### 6 PHTHALATE COMPLIANCE

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

### 7 DUAL USE ADDITIVE COMPLIANCE

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.

### 8 CMR (carcinogens, mutagens or toxic to reproduction) SUBSTANCES COMPLIANCE

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.

### 9 COMPLIANCE with EU Pharmacopoeia 6.3 Chapter 3.1.15 "Polyethylene terephthalate for containers for preparations not for parenteral use"

KÖKSAN PET RESIN K-084 enSave 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 2 below :

Tests	Method	Limits	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
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

Table2 – Tests and results of EU Pharmacopoeia 6.3, Ch. 3.1.15.

Any kind of PET Resin preforms manufactured with this product is recommended for use with foodstuff and for long term storage above 6 months at room temperature or below including heating up to 70°C for up to 2 hours, or heating up to 100°C for up to 15 minutes. The recommended surface to food mass ratio is about 6 dm<sup>2</sup>/kg or l food.

**This declaration is valid for two years from the certificate date and is for material specified above.**